A TEXT MESSAGING APPROACH TO BEHAVIORAL CHANGE, TAILORED USING THE TRANSTHEORETICAL MODEL, IN THE PRIMARY PREVENTION OF TYPE 2 DIABETES MELLITUS IN ASIAN INDIANS

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STATEMENT OF ORIGINALITY

This thesis is submitted to Imperial College, London in fulfillment of the requirements of the degree of Doctor of Philosophy. This thesis represents my own original work towards this research degree and contains no material which has been previously submitted for a degree or diploma at this University or any other institution, except where due acknowledgement is made.

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ABSTRACT

Landmark diabetes prevention trials have shown that lifestyle modification is effective in preventing type 2 diabetes (T2D). In general, information technology with short message service (SMS) and interventions based on behavioral theories of individualized motivation are more effective than non-tailored intervention. The Transtheoretical Model (TTM) is a combination of behavioral theory and stage-based theory. We used TTM-tailored healthy lifestyle and motivating SMS messages as an intervention strategy in a 2-year prospective randomized controlled diabetes prevention trial with two groups (control n=266: intervention n=271) of men with impaired glucose tolerance.

The main objectives were: **1.** To study the utility and acceptability of TTM-based SMS in reducing the incidence of T2D. **2.** To analyse the change in TTM stages in the study groups in lifestyle factors (diet and physical activity practices) with respect to incidence of diabetes at the end of the study. **3.** To analyse the effects of TTM tailored SMS intervention on quality of life and general health and diabetes awareness.

Evaluation tools included: **1.**TTM stages of change inventory for diet and physical activity practices. **2**. SMS acceptability questionnaire. **3**. WHOQOL-BREF (quality of life) questionnaire. **4**. General health and diabetes awareness questionnaire. Questionnaires 1 and 2 were study-specific and developed by the candidate whereas 3 and 4 were standardized. Dietary and physical activity questionnaires had been used in previous diabetes prevention studies in India.

The TTM-based SMS intervention reduced the incidence of T2D (50 [18%] intervention group; 73 [27%], control group (absolute risk reduction 9%)). Significant

differences in TTM stage were observed in the intervention group ($p<0.05$) at six and twenty-four months for dietary practices. Significant differences ($p<0.05$) were observed in physical activity practices only at six months. SMS helped improve quality of life. Significant improvement ($p<0.001$) was observed in general health awareness and diabetes awareness in the intervention group at the end of the study.

The TTM-based SMS intervention was associated with reduced incidence of T2D. The intervention helped improve dietary habits. It also helped improve QOL and general health and diabetes awareness level.

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ABBREVATIONS

A
ADA – American Diabetes Association
ALED – Active Living Every Day
ANOVA - Analysis Of Variance
B
BMI – Body Mass Index
C
CI – Confidence Interval
CAD – Coronary Artery Disease
CVD – Cardiovascular Disease
D
DCCT – Diabetes Control and Complications Trial
DM – Diabetes Mellitus
DPP – Diabetes Prevention Program
DPS – Diabetes Prevention Study
DREAM - Diabetes Reduction Assessment with ramipril and rosiglitazone Medication
E
ECG – Echo Cardio Gram
G
GDM – Gestational Diabetes Mellitus
H
HbA1c – Glycated Haemoglobin
HAPA - Health Action Process Approach
HDL – High Density Lipo protein
HR – Hazard Ratio
HOMA –IR – HOmeostasis Model Assessment of Insulin Resistance
HRQL – Health Related Quality of Life
I
IDF – International Diabetes Federation
IDPP – Indian Diabetes Prevention Program
IDRF – India Diabetes Research Foundation
IFG – Impaired Fasting Glucose
IGT – Impaired Glucose Tolerance
INR – Indian Rupee
IQR – Inter Quartile Range
IT – Information Technology
J
JDPS – Japanese Diabetes Prevention Study

L
Look AHEAD – Action for Health in Diabetes
LSM – Lifestyle Modification
N
NCDs – Non-Communicable Disease
NGT – Normal Glucose Tolerance
NICE – National Institute for Health and Clinical Excellence
NPCDCS – National Programme for Prevention and Control of Cancer Diabetes Cardiovascular disease and Stroke
O
OGTT – Oral Glucose Tolerance Test
OR – Odds Ratio
P
PA – Physical Activity
PAPM – Precaution Adoption Process Model
PG – Post Glucose
Q
QOL – Quality Of Life
R
RR – Risk Reduction
RRR – Relative Risk Reduction
S
SD – Standard Deviation
SEA – South-East Asia
SMS – Short Messages Service
SOC – Stages Of Change
T
T2D – Type 2 Diabetes
T2DM – Type 2 Diabetes Mellitus
TRIPOD – Troglitazone In Prevention Of Diabetes
TTM – Transtheoretical Model
TTM SOC – Transtheoretical Model Stages of Change
U
UKIERI – United Kingdom India Education and Research Initiative
UKPDS – United Kingdom Prospective Diabetes Survey
US – United States
W
WDF – World Diabetes Foundation
WHO – World Health Organization
WHOQOL-BREF - World Health Organisation Quality Of Life BREF

UTILITY OF STAGE BASED BEHAVIOURAL INTERVENTION IN PREVENTION OF TYPE-2 DIABETES

1.1 Introduction

Health is of critical importance in the global agenda. It has become recognized in international forums where once it was not addressed. Diabetes is a huge and growing problem and the costs to society are high and escalating. The global increase in the incidence of type 2 diabetes (T2D) and pre-diabetes is a major challenge to healthcare professionals and policy makers especially in developing countries like India. The recent estimates of the International Diabetes Federation (IDF) indicate that 382 million people (8.3% aged between 40 and 59 years) have diabetes, and this figure is projected to rise beyond 592 million by the year 2035 (IDF Diabetes Atlas 6th edition 2013). Yet, 175 million of diabetic cases are presently undiagnosed, and a large proportion of people with diabetes are unaware of the progression of diabetes complications. These figures provide a worrying indication of the future impact of diabetes as a major threat to global development. The number of people with T2D is increasing in every country; all nations, rich and poor, are suffering the impact of the diabetic epidemic. Indisputably, diabetes is now being recognised as one of the most challenging health problems of the present century. It is one of the most common non-communicable diseases (NCDs) other than cardiovascular disease (CVD). Diabetes and its complications are major causes of early death in most countries and cardiovascular disease is one of the leading causes of death among people with diabetes. There is substantial evidence that it is epidemic in many economically developing and newly industrialized countries. In most countries T2D has increased alongside rapid cultural and social changes: increasing age, rapid urbanization, westernized dietary pattern, reduced physical

activity, and unhealthy behaviors due to modern lifestyle (WHO Report of a WHO Study Group 1994).

1.2 Prediabetes

Diabetes is a clinical state which is preceded by a condition called prediabetes. Prediabetes is commonly referred to as impaired glucose tolerance (IGT) or impaired fasting glucose (IFG), in which blood glucose levels are high but not as high as in diabetes. It is described as a 'grey area' between normal glucose level and diabetes. Prediabetes is also a major public health problem; people with IGT have a high risk for future development of diabetes mellitus (DM) (Report of a WHO Consultation 1999; Clinical Practice Recommendations 2005). In addition, persons with IGT are at an increased risk of cardiovascular disease compared to persons with NGT, and cardiovascular mortality is also higher (Clinical Practice Recommendations 2005). Evidently, IGT shares many characteristics with T2D; it is associated with obesity, progressing age and insulin resistance. However, the good news is that not all persons with IGT progress to develop T2D and there is substantial evidence to support the effectiveness of lifestyle interventions (healthy diet and improved physical activity) to prevent the progression to diabetes (Gillies 2007).

Over the past 2 decades, there has been an improved understanding of the pathophysiological mechanisms of diabetes, which has resulted in the development of new therapeutic concepts, like prevention and management of diabetes through pharmacological agents and lifestyle interventions. The latest estimate of the prevalence of diabetes, and future projections, demonstrates that no community is being spared from the escalating NCDs of diabetes and prediabetes (Diabetes Atlas 6th edition 2013). Hence there is a pressing need to develop effective strategies and

approaches that will prevent the development and progression of diabetes as well as its associated micro and macro vascular complications and also the other NCDs.

Landmark primary prevention trials have suggested solutions for managing and curbing the diabetes epidemic (Eriksson 1991; Pan 1997; Tuomilehto 2001; Knowler 2002; Ramachandran 2006; Ramachandran 2009; Kosaka 2005). These trials have shown that diabetes is preventable in prediabetic individuals with IGT or IFG: lifestyle modification (LSM) through moderate changes in diet and physical activity produce a significant reduction in the incidence of T2D. The studies have also shown that the LSM produces a sustained reduction in the incidence of T2D (Lindstrom 2006; Li 2008; Knowler 2009).

1.3 Lifestyle

Lifestyle is defined as a way of living of the individual or families or societies which they manifest in coping with their physical, psychological, social and environmental challenges on a day-to-day basis. Thus, a lifestyle results from the choices that an individual makes, and the person may make different choices to change that lifestyle. Behaviour includes anything the individual does or experiences. In a narrow sense, behaviour can be defined to include only objectively or publicly observable responses.

Lifestyle changes due to urbanisation and modernisation have caused unhealthy diet habits, sedentary lifestyle or lack of physical activity, and increased stress leading to overweight or obesity with higher levels of insulin resistance. Consequently, the role of lifestyle and behavioural factors in the development of T2D is widely acknowledged. Therefore, the management of this chronic illness must involve not only medication but also lifestyle changes. Such LSM to control diabetes

and coronary heart disease risk factors may be effective in the long term in reducing the tremendous medical and personal costs of this chronic illness and its complications (Eriksson 1991; Barnard 1994).

Primary prevention is defined as the prevention of a disease by controlling modifiable risk factors through population prevention programs (Rose 1985). The non-modifiable risk factors for T2D are age, sex, family history of T2D, genetic predisposition, history of gestational diabetes, and ethnicity. The modifiable risk factors include overweight and obesity, sedentary lifestyle, unhealthy diet, previously identified glucose intolerance, adverse intrauterine environment, alcohol consumption, and tobacco smoking. It is the modifiable risk factors, shown in table 1.1, that are targeted by primary prevention strategies (Alberti 2006).

Table 1.1.The modifiable and non-modifiable risk factors for type 2 diabetes

Modifiable risk factors	Non-modifiable risk factors
Overweight / Obesity	Age
Sedentary lifestyle	Gender
IGT or IFG / Gestational diabetes	Family history
Waist circumference	Ethnicity
Smoking	Polycystic Ovarian syndrome
Hypertension	Intra-uterine growth (thrifty genotype)
Dietary habits	
Stress	

1.4 Need for diabetes prevention in India

Diabetes is undoubtedly one of the most challenging problems of the present century, and it is a rising epidemic in many economically developing and newly industrialized countries like India. Diabetes can be found in every country; however its major impact is seen very much in the South East Asian countries. (S. Wild, G. Roglic, A 2004) Without effective prevention and management programmes, the burden will continue to increase worldwide.(Evaristo-Neto AD) Urbanization and socioeconomic progress occurring rapidly in the Indian subcontinent, is responsible for a considerable proportion of the global diabetes burden. India has the largest number of the persons with diabetes next to China (IDF Diabetes Atlas-Sixth edition 2013). Studies in different parts of India have demonstrated an escalating prevalence of diabetes not only in urban populations, but also in rural populations due to urbanization leading to change in lifestyle. This change in lifestyle resulted in a high prevalence of prediabetes and diabetes. Recent studies (Ramachandran 2001; Mohan 2006; Ramachandran 2008) have shown a rapid conversion of impaired glucose tolerance to diabetes in the Southern states of India, where the prevalence of diabetes among adults was approximately 20% in urban populations and approximately 10% in rural populations. India is varied in social, economic, cultural and educational patterns. Several regions in the country are still under-developed and the people have several myths and beliefs regarding the disease. (R. Shobhana 1999). Because of the considerable disparity in the availability and affordability of diabetes care, as well as low awareness level of the disease, the glycemic outcome in treated patients is far from ideal. The economic burden of treating diabetes and its complications is considerable. Therefore it is appropriate that the Indian Government has initiated a national program for the prevention and management of diabetes and related metabolic disorders and complications (Reference NPCDS). Primary prevention of diabetes is urgently needed in India to curb the rising burden of

diabetes, (Ambady Ramachandran and Chamukuttan Snehalatha 2009) because it poses a medical challenge that is not matched by the budget allocations for diabetes care.

A gene–environmental interaction leads to the final expression of the disease. Although the genetic component cannot be corrected, many of the environmental factors are modifiable. Obesity, high calorie or unhealthy diet, and physical inactivity are the modifiable risk factors. Traditional lifestyles, characterized by diet, including less saturated fat and complex carbohydrates, and greater physical activity may protect against the development of cardiovascular risk factors and diabetes, even in the presence of a potential genetic predisposition.

Lifestyle changes involving major changes in diet patterns, decreased physical activity due to improved transportation, availability of energy saving devices, and high level of mental stress are associated with modernization. Weight gain and decreased energy expenditure contribute further to the existing insulin inertia. Lifestyle transitions in the rural populations have a significant effect on the prevalence of obesity and glucose intolerance. (Ramachandran A, Snehalatha C, 1999; Ramachandran A, Snehalatha C, 2004). The rural prevalence of diabetes has increased from 2.4% in 1989 to 9.3% in 2006. (Ramachandran A, Mary S, 2008) Important risk factors associated with this increase are a lack of physical activity and increased upper body adiposity. Similar observations were reported in Singapore (Lee WWR. 2000) and Malaysia (Mafauzy M, Mokhtar N, 1999)during the stages of urbanization. National and regional heterogeneity in the occurrence of diabetes may be more strongly related to recent environmental events rather than to genetic factors, which change very slowly. (Gerstein HC, Waltman L. 2006) The present generation has easy access to agricultural, industrial, and technological devices that are already developed, unlike older generations. This may explain, in part, the

sudden spurt of lifestyle disorders in urban populations in developing countries. (Sicree R, Shaw J, 2006)

The rural population has limited facilities for appropriate medical care. In the metropolitan cities and towns medical facilities are fairly adequate. As the number of people with diabetes is increasing at a rapid rate, it is necessary to educate the public regarding the disease and clear their misconceptions. Chennai is a metropolitan city with a number of hospitals providing care for patients with diabetes. People have repeated exposures to media; press, television and radio provide key messages on diabetes management and prevention of complications. These sources will also be useful in dissemination of knowledge on the preventive aspects of diabetes. It has recently been demonstrated by us that moderate but consistent lifestyle modification is effective in preventing diabetes in high risk groups (Ramachandran 2006). The results would help us not only to identify the areas to focus but also the population to be targeted to achieve the desirable outcome, especially because of the limited resources available. An action plan is being worked out to educate the general population and also to raise the level of awareness among the diabetic population. Information regarding the disease is increasing and there have been remarkable improvements in the treatment of diabetes and its complications over the years. Efforts have to be directed to disseminate relevant information to the population which hitherto have only been known to the researchers, clinicians and scientific members.

A study conducted by Murugesan et al., in Chennai had indicated that the diabetes awareness level was generally poor in this population. The score was low especially in women and participants with low education. The study highlights the urgent need for strategies to spread awareness about diabetes in the general population. Diabetic subjects also required better education on various aspects of diabetes (N. Murugesan 2007). Another study conducted in Chennai, Southern India, had

shown that awareness and knowledge regarding diabetes is still grossly inadequate in India. (Deepa Mohan 2005) Therefore massive diabetes education programmes are urgently needed both in urban and rural India.

1.5 Feasibility and effectiveness of primary prevention strategies in type 2 diabetes

Studies on primary prevention of T2D conducted in different parts of the world in various ethnic and racial populations have repeatedly shown that T2D is a preventable disease. The onset of the disease can be prevented or delayed in the high risk individuals by controlling the adverse effects of environmental risk factors either by LSM (Eriksson 1991; Pan 1997; Tuomilehto 2001; Knowler 2002; Ramachandran 2006; Ramachandran 2009; Kosaka 2005) or with pharmacologic agents (Knowler 2002; Ramachandran 2006; Gerstein 2006; Chiasson 2002). Persons with IGT and/or IFG or women with a history of gestational diabetes mellitus (GDM) are susceptible to diabetes and have each been studied in these prospective trials.

1.6 Major primary prevention studies using lifestyle modification

Table 1.2 shows the details of the major T2D prevention trials that used lifestyle modification as an intervention strategy.

1.6.1 The Malmo study

The Malmo feasibility study was an early primary prevention study done in Malmo, Sweden in which 217 middle-aged men with IGT (BMI 26.6 kg/m^2) or NGT (BMI, 24.3 kg/m^2) (Eriksson 1991) were recruited. The subjects were distributed into

two groups; they either received standard medical care according to clinical requirements plus intervention with diet and exercise or received standard medical care alone. The intervention group received detailed dietary advice and support within an exercise program. The effects of exercise training and diet modification were compared with the non-randomised group receiving no intervention. The study showed that LSM resulted in a lower incidence of diabetes (10.6% Vs 28%) in the intervention group, ($p < 0.001$) over a period of 5 years. This represents a greater than 60% reduction in the development of diabetes, apparently attributable to the treatment in the 6-year period. No anti-diabetic drug was prescribed to any of these two groups. The 12-year post trial follow up analysis showed that, the mortality rate in the intervention group was lower than in those receiving standard medical care (6.5 and 14.0/ 1000 person years, $p = 0.009$) (Eriksson 1998).

1.6.2 The China Da Qing Study

The Da Qing Chinese diabetes prevention study was conducted in 577 subjects with IGT (Pan 1997). The aim of the study was to investigate the effectiveness of exercise and diet in reducing the conversion of IGT to T2D. The participants were randomized to 4 groups, which were prescribed regulated diet, increased physical activity, improved diet plus physical activity, and/or no intervention (control). At the 6-year follow-up period, all 3 interventions were equally effective in reducing the conversion to diabetes when compared with the control group. The annual risk of progressing to T2D from IGT in this population was reduced from 15.7 to 8%, indicating nearly a 50% reduction in risk as a result of lifestyle changes.

1.6.3 The Finnish diabetes prevention study

The results of the Finnish Diabetes Prevention Study provided the first convincing evidence from a prospective randomised controlled trial that T2D can be prevented by LSM. The study randomised 522 overweight individuals with IGT into either control (advice on general healthy lifestyle at the baseline visit) or an intensive lifestyle intervention group, which received individualized advice and behavioural support (Tuomilehto 2001). In the mean 3.2 years follow up period, intensive lifestyle intervention reduced the incidence of T2D by 58%. The study examined the effect of a healthy diet and exercise program in achieving ≥ 5% weight reduction in prevention of T2D in subjects with IGT. The cumulative incidence of diabetes after 4 years was 11% in the intervention group and 23% in the control group. The extent of the reduction in the incidence of diabetes was directly associated with magnitude of the changes in lifestyle.

1.6.4 The U.S. Diabetes Prevention Program (DPP)

The DPP was a double blind randomised controlled trial conducted in a multiethnic population of the United States, with randomisation of 3234 adults with IGT. The participants were originally randomised into 4 groups to receive: 1) standard lifestyle recommendations with placebo (control group); 2) standard lifestyle recommendation with the widely-used hypoglycaemic drug metformin; 3) intensive lifestyle intervention and 4) the PPAR gamma agonist drug, troglitazone. The latter group was withdrawn within a year because of the adverse effect of the drug (Knowler 2002). The primary aims of the intervention were $\geq$ 7% weight reduction and moderate physical activity for $\geq$ 150 min/week. A healthy, low-calorie, low-fat diet was advised. LSM training was given by individual case managers or “lifestyle

coaches" to the participants assigned to the LSM group, with 74% achieving the goal of 150 minutes or more of physical activity per week at 24 weeks.

The relative risk reduction (RRR) after 2.8 years was 58% in the intensive lifestyle intervention group and 31% with metformin group compared with the placebo treated group.

The results showed that intensive lifestyle intervention (diet and exercise) was significantly more effective than metformin. The lifestyle effect was explained by the change in body weight (Hamman 2006).

1.6.5 The Indian diabetes prevention program (IDPP1 & 2)

IDPP-1: Prevention of diabetes is of utmost importance in India, the country that has the second highest number of diabetic persons in the world next to China (IDF Diabetes Atlas 6th Ed. 2013; Ramachandran 2006; 2009). The escalating prevalence of diabetes in India and other South Asian countries is mostly associated with lifestyle transitions towards urbanisation and industrialization causing adverse environmental effects on an existing genetic predisposition (Ramachandran 2010). The Indian DPP (IDPP) was designed to test whether primary prevention of diabetes was feasible in native Asian Indian people with IGT. 531 participants with persistent IGT (421 men and 110 women) were randomised into control (standard care advice), LSM, metformin (250 gm twice a day) and LSM plus metformin. The primary outcome was incidence of T2D. In the median follow-up of 30 months, the cumulative incidences of T2D were 55.0%, 39.3%, 40.5% and 39.5%, respectively. The relative risk reduction (RRR) was 28.5% with LSM; 26.4% with metformin; and 28.2% with LSM plus metformin compared to control group

The RRRs were approximately 29%, i.e. similar in all 3 individual interventions. LSM was equally effective as metformin in reducing the incidence of diabetes, and there were no additional benefits by combining both. Importantly, the beneficial changes in glycemia occurred without significant reduction in weight.

IDPP-2 (Ramachandran 2009) was another 3-year, prospective study in 407 participants with persistent IGT. Subjects were randomized to either LSM plus 30 mg of the PPAR gamma agonist, pioglitazone, or LSM plus placebo. The aim was to test whether combination with pioglitazone would enhance the effectiveness of LSM in reducing the incidence of T2DM. At the end of 3 years, the cumulative incidence of diabetes was 31.6% in the placebo group and 29.8% in the pioglitazone-treated group. Normoglycemia was achieved in 32.3% and 40.9% of participants who received placebo and pioglitazone, respectively (P = .109). There was no added benefit on glycemic outcome by combining pioglitazone with LSM. The most probable explanation for this observation was that the maximum possible benefit on pathophysiology was produced by LSM and no additional improvement could occur by adding an insulin sensitizer. This finding was at variance with that of the Diabetes REduction Assessment with Ramipril and Rosiglitazone Medication (DREAM) study, (Gerstein 2006) which showed a significant relative risk reduction in incident diabetes with rosiglitazone therapy in participants with IGT and/or IFG in all ethnic groups. However, the treatment effect significantly differed by ethnicity, with South Asians experiencing a smaller effect, and Latinos experiencing a larger preventive effect. An ethnicity-related difference in the action of glitazones in nondiabetic persons may have been responsible for the differences in outcomes.

1.6.6 The Japanese diabetes prevention study

A 4-year prospective study randomized 458 Japanese men with IGT to either a control group with standard care advice or to an intensive lifestyle intervention with diet and exercise group. The intensive lifestyle intervention group was offered repeated motivation to maintain healthy lifestyle with the intention of reducing BMI to less than 22 kg/m^2. The risk reduction in the intervention relative to the control group was 67.4% (Kosaka 2005). Although there was a significant correlation between the incidence of diabetes and the degree of weight reduction, the reduction in body weight did not fully account for the beneficial effect.

These studies have shown that LSM is an effective preventive strategy in subjects of varied ethnicity, in men and women, and in overweight (Knowler 2002) or lean subjects (Ramachandran 2006). However, there may be racial variations in effectiveness. Prevention of T2D requires lifestyle changes related to physical activity and diet behaviour. Healthy diet, regular physical exercise, and avoidance of smoking and excess alcohol consumption are emphasized. The principles of LSM are sustained physical activity of $\geq$30 min/wk on all days of the week, with an absolute minimum of 5 days a week, plus restricted calorie intake, with reduction of refined carbohydrate and fat content and inclusion of food fibre (Lindstrom 2010). Reduction of weight in obese persons by intensive practice of LSM has shown beneficial effects. Overall, the published information of the effect of lifestyle changes is encouraging, with at least a 50% reduction in progression from IGT to T2DM.

Table 1.2. Major primary prevention trials in type 2 diabetes using lifestyle modification

Study**	Study participants characteristics	Number of participants by treatment group	Duration of intervention (years)	Lifestyle goals	Behavioural interventions used	Weight reduction achieved	Cumulative incidence of diabetes (%)	Risk reduction (95% CI)
Da Qing Pan et al (1997)	Chinese Mean BMI: 26 kg/m^2 Mean age: 45 years	Diet (130) Exercise (141) Diet + Exercise (126) Control (133)	Mean 6 years	Weight loss and maintenance of healthy diet and / or exercise	Group counselling, Individual counselling sessions, Goal setting	Non-significant	Diet: 43.8 Exercise: 41.1 Combined: 46.0 Control: 67.7	Diet - 31% Exercise – 46% Diet + Exercise – 42%
Diabetes Prevention Study Tuomilehto (2001)	Finnish Mean BMI: 31 kg/m^2 Mean age: 55 years	Diet + Exercise (265) Standard care (257)	Mean 3.2 years	5% weight loss on low fat, high fibre diet + 30 min exercise per day	Individual counselling sessions, Supervised exercise session, Goal setting,	-4.2 vs. -0.8 kg; P<0.001	LSM: 11 Control: 23	58% (30 – 70%)
Diabetes Prevention Program (DPP Research Group 2002)	Multi-ethnic Mean BMI: 34 kg/m^2 Mean age: 50.6 years	Diet + Exercise (1,079) Standard care (1,082)	Median 2.8 years	7% weight loss + 150 min of exercise per week	Face to face group counselling, Individual initial counselling sessions, Supervised exercise program, Goal setting	-5.6 vs. -0.1 kg; P <0.001	LSM: 4.8 Control: 11	58% (48 – 60%)
Japanese Diabetes Prevention Program Kosaka et al (2005)*	Japanese men Mean BMI: 24 kg/m^2 Mean age: 51.5 years	Diet + Exercise (356) Standard care (102)	Mean 4 years	Reduction in BMI to $\leq$ 22kg/m^2 by 30-40 min of exercise per day	Individual educational session, Individual goals for diet and exercise	2.2 kg vs. 0.39 kg; P <0.001	LSM: 3.0 Control: 9.3	67.4%
Indian Diabetes Prevention Programme-1 Ramachandran et al (2006)	Japanese men Mean BMI: 24 kg/m^2 Mean age: 51.5 years	Diet + Exercise (133) Control (135)	Median 2.6 years	Weight maintenance by restricting refined carbohydrates and fat + 30 min of exercise	Individual counselling, Individual goals for diet and exercise	Non-significant	LSM; 39.3 Control: 55	28.5 (20 – 37%)

1.7 Benefits of behavioural intervention

Studies (Tuomilehto 2001; Kitabchi 2005; Snehalatha 2009) have shown that lifestyle changes involving increasing physical and healthy dietary practices are associated with improvement in insulin sensitivity and beta cell function which promote prevention of diabetes. One study (Snehalatha 2009) has also shown that improvement in insulin sensitivity and beta cell function can also occur even without weight reduction. Physical activity is recognised as one of the most important lifestyle factors, results in improvements in insulin sensitivity. The International Diabetes Federation (Alberti 2007)and American Diabetes Association recommends, ≥ 30 minutes of moderate to vigorous physical activity for at least 5 days a week with dietary modifications to include: restriction of total calories, sweetened beverages, refined carbohydrates and high saturated fats and fibre rich foods. Studies (Li 2008; Kowler 2009; Lindstrom 2006) have shown that diabetes can be prevented by following healthy lifestyle practices for at least 10 years.

1.8 Pharmacological agents in the prevention of T2D

Several landmark diabetes prevention trials tested pharmacological agents in parallel with lifestyle intervention. The Da Qing study evaluated the effects of diet and exercise, acarbose and metformin (750 mg/day) on the incidence of T2D in 321 IGT subjects. The study showed beneficial changes with metformin and acarbose-treated groups. The Relative Risk Reduction (RRR) was 77% with metformin, 88% with acarbose. The DPP Research group used metformin (1700 mg/day) in the prevention of T2D. The study resulted in a 31% RRR in the incidence of T2D in subjects with IGT, but its effectiveness was lower compared to that of intensive LSM (58%). Insulin sensitising thiazolidinediones were also tested in some trials.

However, as described previously, these drugs offered no improvement over LSM; they may also have a relatively poor safety profile.

Studies using pharmacological agents have shown the potential use of oral hypoglycaemic agents for prevention of T2D. However, the only drug which may be considered as a safe preventive oral hypoglycaemic agent is metformin (Alberti 2007) and, in some trials, even this has been shown to have little additional value beyond LSM. Table 1.3 shows the advantages and disadvantages of LSM Vs pharmacological agents in the prevention of T2D.

Table 1.3 Lifestyle modification Vs Pharmacological agents

Effects of intervention	Lifestyle modification	Pharmacological agents
Sustainability	Long lasting benefits	Short duration; the effect ceases once the drug is withdrawn (except troglitazone in TRIPOD study)
Risk reduction	Very high	Low to moderate
Benefit / Risk ratio	Very high	Low to moderate
Adverse effects	Safe; no adverse events reported in any clinical trial	Not safe; adverse events such as CVD risk, mortality, edema and gastro-intestinal side-effects reported
Adherence	Low to moderate; because it involves very stringent diet and physical activity regiment	Moderate adherence to pharmacological prescriptions
Acceptability and compliance	High, less than 10 - 15% dropout rate reported in almost all prevention programme	Moderate to high; in few studies more than 50% dropout rate reported because of side effects
Treatment cost	Low	High (Lower if the drugs are sold in generic pricing)

1.9 Diabetes in South-East Asia

The South-East Asia region is comprised of seven countries. Close to one-fifth of all adults with diabetes in the world live in the South-East Asia region. Current estimates indicate that 8.2% of the adult population, or 72.1 million people, have diabetes, 65.1 million of whom live in India. The number of people with diabetes in this region will increase to 123 million by 2035 – 10.1% of the adult population. A further 24.3 million people have IGT, and this will increase to 38.8 million by 2035. This escalating rate of diabetes and IGT in India is mainly attributed to the economic growth rate experienced by this country (The World Factbook 2013).

1.10 Economic burden

Diabetes places an economic burden on those living with the disease, and their families, and ultimately, entire national health systems, thus threatening economic development. It has been estimated that in 2013, the worldwide total health expenditure on diabetes was 10.8% (IDF Diabetes Atlas, 6th ed). This expenditure includes medical spending on diabetes by health systems, as well as by people living with diabetes and their families. People living in low and middle income countries pay a larger share of their income on health expenditure compared with those living in high income countries, primarily because of lack of access to health insurance and to government-provided free medical services.

1.10.1 Economic implications

Although the goal of diabetes prevention programs is prevention of T2D, the primary objective of the prevention studies is to develop a strategy that is cost-effective and offers high cost-benefit when implemented in large scale community programs. The primary goal of the DPP and other major diabetes prevention trials

was to establish whether intensive lifestyle changes (ILC) or pharmacological interventions could significantly reduce the incidence of T2D in people with IGT. Only DPP and IDPP-1 (Knowler 2002; Ramachandran 2006) analysed the cost-effectiveness of diabetes prevention. Both studies indicated that LSM would be more cost-effective than pharmacological intervention with metformin. The DPP Research group estimated that from the health care perspective, to prevent one case of diabetes in the United States, the intensive LSM intervention cost was $15,700 and the metformin drug treatment cost was $31,000 (The DPP Research Group 2003). Although the cost of prevention in the DPP study was high, the overall expense incurred in prevention was cost-effective in the context of U.S. society. Preventing diabetes is of huge value for the Indian scenario because the cost of diabetes care is relatively high for Indian conditions. On average, an individual with diabetes spends Indian rupee (INR) Rs 10,000 (US $227) for diabetes management in an urban area per year (Shobhana 2000). In IDPP-1, the LSM cost was $1052 to prevent or delay one case of diabetes (Ramachandran 2007). If diabetes can be prevented or delayed with LSM, the prevention program would result in a net benefit in health care investment. Thus, diabetes prevention represents good use of health care resources in India and perhaps in other developing countries as well.

The apparent implication of these findings is that early intervention by LSM to prevent or postpone the onset of T2D could be of enormous benefit, both to patients in terms of increasing life expectancy (LE) and quality of life, and potentially in economic terms for society, and healthcare professionals and policy makers. However, these interventions are not widely used.

Although the initial costs of a diabetes prevention trial may place a major economic burden on health care resources in the short term, it is hypothesized that the potential for long-term cost savings from the prevention or delay of the disease

would easily outweigh the initial expenditure. There is widespread acceptance of the effectiveness of diet modification and physical activity in the prevention and management of T2D (Pastors 2012; Balducci 2012; Herman 2005; the DPP Research Group 2005). This is reflected in the Canadian (Canadian Diabetes Association 2008), UK NICE (NICE clinical guideline 2009) and Australian guidelines (Colagiuri 2009) as well as the ADA standards of medical care (Balducci 2012; American Diabetes Association 2012; 2008). However, LSM can be difficult to achieve and maintain (NICE clinical guideline 2009). Most lifestyle intervention studies have been short-term (although this is currently being addressed by the 12 year prospective Look AHEAD study (The Look AHEAD Research Group 2007). Other considerations include a lack of knowledge about the ongoing contribution of lifestyle measures once medication has been introduced, or what kind of support is required on a continuing basis. Importantly, the UKPDS initial nutrition intervention was very effective in lowering blood glucose after diagnosis of diabetes and some people were then able to maintain target glucose control for many years by nutrition modifications alone (UKPDS 7 1990; Turner 1999). However, eestablished prevention strategies in individuals at high risk of T2DM have involved frequent, personal contact, advice and counselling, all of, which is highly labour intensive. Although the strategy of diabetes prevention through LSM has proved to be cost effective, still there is a pressing need to establish alternative strategies that can be more widely and economically applied. The current need is to develop simple, pragmatic and inexpensive methods to identify high risk subjects and to develop novel and innovative approaches which can be used and implemented effectively at the community level in the prevention of T2D. This need underlies the proposed use of SMS technology according to which motivational messages delivered by mobile phone could be communicated to large number of people at-risk for developing diabetes. Moreover, by combining this strategy with individualised messages,

according to a proven behavioural theoretical method, effective prevention of diabetes may be even further advanced. If this methodology is found to be effective and cost effective then this approach could be applied at the national level.

1.11 Background of the study

1.11.1 Objectives and Scope of Behavioural Interventions

Interventions to change lifestyle have been found to be effective in preventing diabetes as shown by all the major landmark diabetes prevention programmes. The evolution of behavioural intervention began with behavioural counselling in a clinic or a primary care centre on a one-to-one basis. Later it was developed to deal with any individual problems through telephone contacts and now it is further developed as personalised mailing through internet e-mail delivering self-help guides or materials. Behavioural counselling is a broad area which covers a wide array of preventive and therapeutic activities, from mental health to marital therapy. Recently, the concept has been focused on an individual's more specific problems e.g. physical inactivity or eating disorder and thereby offering health education and behaviour change support to overcome these problematic behaviours. The behaviour counselling concept was introduced into many randomised controlled clinical trials to help subjects change in their health-related behaviours and to prevent lifestyle disorders. This focused use of behavioural counselling has led to introduction of the term 'behaviour counselling intervention'. Behaviour counselling intervention here refers to a way of work demanding equal commitment from the subject and researcher that aims to facilitate the participant's personal initiative and ability to cope with the new behaviour on a long-term basis (Nupponen 1998).

1.12 Stages theories and stage transitions

Theories are used to explain the physiological and psychological determinants of behaviour and to guide the progress and improvement of health promotion and educational efforts. Health behaviour theories focus on various factors of behaviour at the individual, interpersonal, community, and/or societal levels (Glanz 1996). A recent meta-analytic review of tailored print health behaviour change interventions by Noar and colleagues had suggested that, tailoring interventions to behavioural stages is more effective than generic, not stage-tailored interventions (Noar 2007).

In recent times, stage theories of health behaviour have gained in importance in health research. The concept behind the application of stage theory is that, people passing through an ordered set of behaviour qualitatively at different stages (Weinstein 1998) on their course to decide, start and sustain healthy behaviour. health-related behaviours is both instinctive and appealing for the plan of interventions (Brug 2004). This process includes the possibility of moving forward or relapsing to a previous stage (Prochaska 1992). The primary outcomes in stage theories are shift in stage i.e. stage transition rather than behaviour itself because in previous stages no behaviour was performed by the individual. The notion that the stages differ qualitatively, implies that a number of variables that may help drive individuals through the stage transition includes: increased positive perceptions and decreased negative perceptions of making the health behaviour change (Prochaska 1994), increased self-efficacy that one has the skills and abilities to make the change (Prochaska, Redding, & Evers, 2002), and a variety of cognitive and behavioural change strategies or processes of change (Prochaska 1992). These features distinguish stage theories from social cognition theories such as theory of planned

behaviour [TBP; (Ajzen 1991)] which construe behaviour change as a continuous process.

The most widely applied stage theories include: the transtheoretical model (TTM; [Prochaska 1992]), the precaution adoption process model (PAPM; [Weinstein 1988]), the I-Change model (De Vries 2005; 2003), the health action process approach (HAPA; [Lippke 2005; Schwarzer 1992]) or the model of action phases (MAP; [Heckhausen 1987].

1.12.1 Transtheoretical model

The Transtheoretical Model (TTM) is a behavioural theory which is widely applied in health research for interventions in the health problems of individuals. Interventions are based on the individual's so-called 'TTM stage'. The TTM was developed by Prof. James O. Prochaska and his colleagues from the University of Rhode Island, Kingston, U.S.A. in 1977 (Prochaska 2005). It derives from an analysis of a range of different theories of psychotherapy (Prochaska; Systems of psychotherapy: a transtheoretical analysis 7th ed.) and is therefore termed the 'transtheoretical model'. Based on subsequent research between 1980 and 2010, Prochaska and his colleagues have refined the theory, which is now an established tool in behavioural change studies (Prochaska JO, A transtheoretical analysis 7th edition).

The original research context for this theory was in negative addictive behaviour such as smoking and the research identified 'self-changers' who could change successfully without professional intervention (Prochaska 1983; Prochaska 1999). Across 12 health behaviour theories, (Prochaska 1994) the TTM model has been used in various studies and is cited by Samuelson (Samuelson 1997) as one of

the most important theories of the decade in the promotion of health. TTM offers a theoretical explanation of the processes involved when a person is attempting to change his or her problematic behaviour or acquire a positive behaviour. The 4 core constructs of the model are the “stages of change,” “process of change,” “decisional balance,” and “self-efficacy” (Prochaska 1997). The stages of change (SOC) is the main construct of this model and demonstrates the “steps involved” in progressing to the desired behaviour (Velicer 1998). The process of change undertakes to explain how individuals change their behaviour and includes cognitive, affective, evaluative and behavioural strategies that an individual may adopt to modify their problem behaviour.

The transtheoretical model is designed to be effective in individuals with problematic behaviour. The role of the researcher is then to use the model to help to identify and work with individuals who are not practicing healthy lifestyle behaviour. The model emphasises how, in helping the individuals with undesired behaviour to adopt a desired behaviour, the researcher identifies their TTM stages the better to plan and tailor the intervention strategy to bring positive behaviour into the individuals’ lives. One study has successfully demonstrated that combining TTM stages and process of change can guide the researcher appropriately for physical activity intervention (Marcus 1998).

Over the last two decades there has been a substantial increase in the application of TTM in exercise behaviour modification studies. However, the majority of studies were conducted in limited population groups, for example middle-aged to elderly populations. Nevertheless, most of these studies were behavioural intervention-oriented and highlighted the significance of different constructs from the TTM in helping sedentary individuals be more active (Dunn 1999; Steptoe 1999).

1.12.2 Transtheoretical model; Stages of change

In the transtheoretical model, change is a "process involving progress through a series of stages" (Prochaska 1992; Prochaska 1997a; Prochaska 1997b)

- **Precontemplation (Not Ready)** - "People are not intending to take action in the foreseeable future, and can be unaware that their behaviour is problematic"

- **Contemplation (Getting Ready)** - "People are beginning to recognize that their behaviour is problematic, and start to look at the pros and cons of their continued actions"

- **Preparation (Ready)** - "People are intending to take action in the immediate future, and may begin taking small steps toward behaviour change

- **Action** – "People have made specific overt modifications in modifying their problem behaviour or in acquiring new healthy behaviours"

- **Maintenance** – "People have been able to sustain action for a while and are working to prevent relapse"

- **Termination** – "Individuals have zero temptation and they are sure they will not return to their old unhealthy habit as a way of coping"

In addition, in the course of this research, "relapse" (recycling) has been conceptualized; this is not a stage in itself but rather the "return from action or maintenance to an earlier stage.

All the previous diabetes prevention programmes (Pan 1997; Tuomilehto 2001; Knowler 2002; Ramachandran 2006; Ramachandran 2009; Kosaka 2005) have involved multiple personal contacts with the participants by healthcare professionals. The trials' successes have resulted from the investigators' ability to motivate participants through individualised input, which is highly labour intensive. Reasons for healthcare professionals not using this individualised input (or lifestyle counselling) might be lack of behavioural counselling training, inability of the health care professionals to spare time on behavioural counselling, shortage of trained multidisciplinary staff, inadequate infrastructure and cost associated with more frequent visits (Digenio 2009). The present healthcare systems in the Indian sub-continent are lacking in all these aspects and have limited resources and capacity for facilitating self-management of disease, including lifestyle interventions. Attempts at LSM without intensive motivation through personal counselling have been unsuccessful. Intensive input is expensive. As a result researchers have started to explore alternative methods of providing lifestyle counselling intervention in an ethical, pragmatic and economic way to translate the trial results into practice for the population at large.

A new system for the management of chronic disease risk that allows patients to control their healthcare in real-life situations is required. Information technology (IT) such as telephone contact, Internet and e-mail-delivered interventions or a mobile phone short-message service (SMS) have been found to be effective alternatives, which could reduce the demand of personal behavioural counselling programs, improve patient compliance and reduce costs (Hellerstedt 1997; Tate 2001; Tate 2003; Hurling 2002). The high rate of mobile phone use in India renders this an appropriate medium for this country. Based on the literature (Fjeldsoe 2009; Krishna 2008) it is found that emerging technology such as mobile phone text

messaging services offer another inexpensive, economical and well-accepted method to send and receive text messages containing healthy lifestyle reminders.

1.13 Behaviour change interventions facilitated by mobile phone text messaging services

It is a continuous task for health care professionals to offer long term, sustained health improvements to their patients in the managements of chronic disease such as T2DM. Quality and effective treatment requires repeated contacts between the health care provider and the patients (Institute of Medicine, Washington DC 2001; Wagner 1996). Finding a new way to improve the contact between these is again an important issue. Intervention strategies using automated telephone message systems have been demonstrated to improve knowledge among participants and better health improvements (Krishna 2002; Piette 2000; Piette 2001). Telephone-based interventions have had favourable outcomes among low socioeconomic groups and ethnic minorities (Albright 2005).

In a chronic disease such as T2DM, to monitor and maintain blood glucose levels and other physiological conditions of the patient requires regular monitoring through self-care behaviours. In this respect, internet e-mail technology-based interventions are already playing a vital role in the quality of diabetes care (Balas 2004). Diabetes education and management through automated telephone reminders have been shown to improve the diabetic patient's knowledge and self-care behaviours. This strategy also helps the diabetic patients who have a specific need for regular self-care and monitoring for better health outcomes (Boren 2006) since this requires continuous support from a health care provider to achieve desired goals. The use of a cell phone text messaging service is a step towards educating patients on self-monitoring and management and also supports feedback about their

present health condition and better management between scheduled clinic visits. The ever-present nature of cell phones provides the opportunity to receive health care advice anywhere at any time instantaneously for the better management of the disease (Boland 2007).

The application of SMS in behavioural research is relatively new. However there is already quite extensive research demonstrating the use of SMS to remind subjects about medical appointments (Bos 2005; Downer 2005; Milne 2006; Viella 2004; Coher 2008), to co-ordinate medical staff (Sherry 2002), to deliver medical test results (Pal 2003; Tomnay 2005; Menon Johansson 2006) and to monitor patient side effects following treatment (Weaver 2007).

The SMS intervention research strategy may be particularly useful among people who use mobile phones as their main source of communication. This medium allows the person, personally to send and receive short messages (maximum 160 characters) to any place, at any time or in any setting immediately according to individual convenience. This is a quantifiable interaction between the researcher and the subject which can be monitored, measured and compared for effectiveness of the intervention. The accessibility of SMS communication may also make it more effective than other telephone or print-based interventions (Atun 2006; Sherry 2002)

Most of the studies to date have been conducted in relation to clinical care interventions with a view to improving the compliance level of the patient; only very few studies concentrated on preventive health behaviour using SMS as a reminder tool (Fjeldsoe 2009). As summarised in a review (Krishna 2008) on diabetes self-management care via cell phone, some studies showed cell phones and text messaging facilitated regular treatment advice and support in between clinic visits. In other studies, cell phones and text messaging proved to be effective tools for

delivering regular alerts and reminders to achieve desired goals. Nine of the 10 studies that used cell phone technology for education, care and support of the patient showed significant decreases in HbA1c values among those who received care and support through cell phone.

Since mobile phone SMS technology is highly accessible to all socio-economic groups it acts as a primary source of information or as a knowledge delivery medium for health behaviour change interventions among people with poor health or unhealthy lifestyle. As more and more people start using cell phones, SMS technology may be found to be a more cost effective mode of communication than conventional telephone communication and may be combined with other methods to educate and support people with poor health and unhealthy lifestyle (Gimenez-Perez 2002; Leong 2006)

Intervention studies have showed that lifestyle counselling based on behaviour change models is more effective in promoting long-lasting behaviour change than traditional counselling (Whitlock 2002). In a review (Fjeldsoe 2009), only 4 of the 14 studies described used theory-based interventions. Theories used included Social Cognitive Theory (Franklin 2006), Behavioural Self-Regulation Theory (Obermayer 2004), Relapse Prevention (Robinson 2006) and a combination of social psychological theories (Hurling 2007). Of the 14 reviewed SMS interventions, 13 demonstrated positive behaviour changes, although some studies (Obermayer 2004; Vahatalo 2004; Franklin 2006) were small and, most likely, too underpowered to show statistically significant results. Components of intervention strategies that have been found to be effective are: goal setting (Whitelaw 2000), tailoring of the program specifically to participants (Prochaska 2003; Van Slujis 2004), the use of written materials (Prochaska 2003; Hee-Seung Kim 2007) and

continued subject therapist contact, whether in person or by telephone, mail or email (Yoo 2009).

Study involving nurse or dedicated study facilitator-led short messaging services (Kim et al., 2007; Kim 2007; Yoon 2008) indicates that SMS improved HbA1c and 2-h post meal glucose levels over a period of 12 months in people with T2DM. These studies also concluded that web-based management systems can be as effective as face-to-face guidance and treatment. Furthermore, the internet has been suggested as a medium for delivering population-based physical activity (PA) intervention (Rodgers 2006), and 50 percent of studies involving internet delivered PA interventions reported an increase in PA. Moreover, theory-based interventions resulted in more positive PA outcomes than interventions not supported by a theoretical model (Rodgers 2006). For instance, the commercial internet PA programme 'Active Living Every Day (ALED) PA' is a behaviour change programme based on the transtheoretical model (TTM) and social cognitive theory (Vahatalo 2004) and has been effective in improving cardiometabolic risk factors in sedentary adults.

The evidence and considerations reviewed above justify a test of the hypothesis that a transtheoretical model-based LSM programme (or 'behavioural change programme') focused on persons who are at high risk for developing T2DM, using mobile phone text messaging services as a motivating tool, will promote lifestyle change. Secondly, it is intended to study the acceptance of text messages as a motivating tool for lifestyle change.

1.13.1 Promoting healthy behaviour through text messages

Unhealthy and risky behaviors such as poor nutrition, lack of physical activity, smoking, and sexual practices, can lead to chronic diseases, including, for example, diabetes, cardiovascular disease, obesity, hypertension or cancer. Individuals who develop such chronic diseases may also be more prone to non-adherence in the management of their diseases (Bryden 2003). The need to positively influence the voluntary aspect of unhealthy behaviors in these non-compliant individuals is an important public health topic.

In recent years there is an increased use of technology in the health care industry. Technology-supported healthcare delivery has reached all corners of the world, irrespective all socio-economic disparities other than internet or email technology service.

There is a wide variety of information technology modes such as e-mail, interactive Web sites, and social networking sites such as MySpace, twitter and Facebook and these have been investigated or considered for investigation in the field of health research. Among these IT-based approaches, cell/ mobile phones have particular potential as cost-effective portals for promotion of healthy behavior that can reach people of all class. Cell phones may therefore provide the maximum opportunity for personalized, private, and easily accessed information through the delivery of short message service (SMS).

Several studies (Franklin 2008; Levine 2008; Obermayer 2004; Samith 2011) have shown promising results in terms of SMS or text messaging use, but few demonstrate significance between text messaging interventions and positive health behaviors or health outcomes. Moreover, few have evaluated the potential for theory-

based text messages as a health intervention strategy to elicit positive behavioral responses.

1.13.2 Text messaging use

In 2007, 255.4 million wireless cell phone users existed in the United States (http://www,cdc.gov/nchs/data/nhis/earlyrelease/wireless200905.htm. December 5, 2009). Recent data shows an increase of 350% in text messaging over a 1-year period: from 81 billion text messages to 363 billion sent and received (http://www.cdc.gov/nchs/data/nhis/early release200905.htm/ December 5, 2009). Cell phones are used across all socio-economic groups, with 71% of teens and 77% of all of US adults owning a mobile phone in 2008 (Lehart 2009). Worldwide, cell phone use continues to expand, with the United Nations recently estimating that 57% of people in developing countries are now cell phone subscribers. The latest annual report (2012-13) of the telephone regulatory authority of India has shown that 867.80 million people are using mobile phones in India (www.trai.gov.in)

1.13.3 Health prompts via text

The ease and accessibility associated with SMS, along with the ability to receive and send brief, private, and personalized messages or reminders has made it widely used and accepted in a variety of health promotion interventions, such as smoking cessation, sexual health, diabetes and medication management, nutrition, and physical activity among various age groups. In a study by Gerber et al (Gerber 2009), women receiving personalized text messaging related to exercise and healthy food choices showed a high level of SMS interactivity and acceptability. However, the study stopped short of measuring associated health or behavioral changes.

Short-text messaging has also shown promise as a means of obtaining pertinent, real-time health information. For example, in a public health effort by Levine et al., to address increasing gonorrhea rates, San Francisco implemented a text messaging sexual health 'info line' via a private 5-digit access number that provided timely information on sexual health topics such as pregnancy, HIV, and sexually transmitted infections that could be easily deleted by the recipients. In a follow-up focus group of 15 to 19-year-olds using the system in the San Francisco area, there was broad support and acceptability. Additionally, SMS usage to access sexual health information was much greater than expected by its developers (Levine 2008). However, this study did not measure behavioral changes or improved health outcomes, such as reduced sexually transmitted infections, among systems users. Other studies in adult populations have evaluated the acceptance and effectiveness of SMS as a reminder portal and have demonstrated improvement in patient adherence to time-sensitive positive health behaviors such as monitoring immunosuppressant therapy and keeping clinic appointments (Ludlow 2009; Leong 2006).

Chronic disease management studies have also shown that more positive patient responses can be obtained by using SMS support. For example, Yoon and Kim (Yoon 2008) evaluated an SMS intervention in adult Koreans with T2D. Participants in the intervention arm were required to enter weekly data via SMS or the Internet, while those in the control group received usual care by their primary care provider. Tailored feedback on blood glucose (BG) was delivered via SMS and included dosing, diet, and exercise recommendations, along with positive reinforcement for good control. Additionally, if weekly results were not entered, SMS reminders to enter glucose information were delivered. Participants not submitting BG levels for ≥4 weeks were dropped from the study. Although small, the eventual

study sample size remained powered for significance. Study results showed that the intervention group had a greater HbA1c reduction as compared with the control group who received no text messages. Additionally, the intervention group's postprandial BG was reduced when compared with the control group. Although this study was limited by its size and generalizability, the results support further exploration of SMS as a tailored, efficient health communication portal to improve chronic disease management adherence.

Despite numerous studies detailing text message use and acceptance in a variety of populations, relatively few research studies have evaluated whether or not SMS interventions influence or change health behaviors among adolescents and young adults, who are not only avid users of mobile phones but are also a uniquely dynamic population prone to risky behavior and non-adherence in chronic disease management - with subsequent negative health outcomes (Bryden 2003).

1.14 The rationale of SMS intervention strategy in India

Mobile health (mHealth) and its components such as SMS, have been touted as one of the many tools that can improve health outcomes through ready access to quality of health services around the world (NIH Office of Behavioral and Social Sciences Research, 2011). This is largely due to the pervasive nature of cellular telephone mobile technology, affording access over 87% of the world (International Telecommunications Union, 2011), which provides near universal access to people regardless of demographic factors or geographic location. Continuingly evolving, people have embraced mobile technology into their everyday lives. Because text messaging is such a ubiquitous medium of communication, it can allow providers to easily reach and deliver care directly to their patients. Although SMS intervention strategy shows promise as a beneficial tool we must be careful of technology-driven hype. This technology, in and of itself, is only a communication medium; it must be

matched with theory driven content and tested in randomized controlled trials to determine its efficacy in improving health outcomes. Human behavior, health, and illness are multifaceted and influenced by numerous factors ranging from environmental, social, to biological. Combining mobile technology with health care will not be an easy achievement and many questions remain unanswered. For every behaviour that SMS methodology is proposed to improve, we must know the appropriate content, how and when to deliver it, and the effects over time.

According to the latest report of Telephone Regulatory Authority of India (TRAI), at the end of the financial year 2012-13, the number of telecom subscribers was 898.02 million, out of which 867.80 million were wireless subscribers. Addressing the seminar on "The Role of Health Informatics - How Health is making a difference to ordinary people in India" at Healthcare & Life Sciences Global Business Summit, in London the former Union Minister of Health and Family Welfare said that mobile telecommunications have seen tremendous growth in India. This growth has been inclusive with benefits accruing to the poorest households in the remotest regions of the country. In 2011 alone, 142 million mobile-cellular subscriptions were added in India, twice as many as in the whole of Africa, and more than in the Arab States, Commonwealth of Independent States (CIS) and Europe put together. The mobile tariffs in India have become among the cheapest in the world.

Recognizing the penetration of mobile phone usage in the society and its potential to reach out to people of all socio-demographic positions, especially those living in remote areas, it is planned to integrate and enhance health behavior through mobile technology which is commonly known as mobile health or mHealth. The SMS technology is easily accessible and robust, and minimal training is needed to use the application. The potential of SMS may be particularly significant among population

groups most likely to use mobile telephones as their primary means of communication. Communication with SMS may also be more cost effective than other telephone or print-based interventions. (Atun R, Sittampalam S. 2006, Sherry E, Collordi B. 2002) From the health care perspective, the SMS technology aids communication with grass roots level health care services providers, health and family welfare policy makers, health managers and health administrators at different tiers of the health care delivery system. In India, one of the best examples of mobile technology was its use in communicating with the 3.2 million Central Government Health Services (CGHS) beneficiaries spread across the country. These beneficiaries are patients who come to the CGHS Wellness Centres for consultation and receiving medicines for treatment. Under the support of the National Rural Health Mission, mobile telephone based systems are being increasingly used for managing health care systems.

Besides the above initiatives, the Government of India is planning a mobile-based information dissemination programme. Through this initiative, health promotion messages could be sent out as and when required for maternal & child health, nutrition for children, adolescent health and population stabilization, tobacco control, information on non-communicable diseases & healthy lifestyle and HIV/AIDS.

Therefore, the objective of this diabetes prevention programme is to reposition the role of the mobile phone from a mere voice communication device to an instrument of empowerment delivering short healthy lifestyle messages (maximum 160 characters) instantaneously directly to the study participants at any time, place, or setting. These messages are asynchronous, meaning they can be accessed at a time that suits an individual. The SMS were developed aimed to help individuals to change and follow healthy lifestyle actions to prevent diabetes.

If this SMS strategy is found to be effective in motivating and changing an individual's lifestyle in the prevention of T2DM then it is intended that the results will be translated to the community at large by highlighting the importance of tailored SMS in health care. They will also benefit governmental and non-governmental health care professionals and policy makers with opportunities for collaboration and development of meaningful partnerships between health care system and information technology (mobile technology) to improve upon health care delivery.

Table 1.4. Shows the trials using SMS as an intervention strategy in disease prevention

Study	Behavior	Research design and participants	Intervention	Intervention effects
Rodger (2005)	Smoking cessation	Design: RCT Sample: 1705 smokers Setting: New Zealand public Recruitment: proactive Participant retention: 74% Main outcome measure: self-report – specific measure not reported	SMS initiation: researcher Format: daily, individually tailored SMS messages sent providing personalized smoking cessation advice, support, and distraction Supplementary materials: nil Duration: 26 weeks Interactivity: high	Impact outcomes: more participants reported not smoking in the intervention group (28%) compared to the control group (13%) at 6 weeks ($p<0.0001$) and 12 weeks (29% vs. difference between groups ($p=0.4$). Process outcomes: high participant attrition rates in study evaluation (74% remained at 26 weeks) Calculated effect size: insufficient data reported Outcome overview: between group, significant, positive change in smoking cessation
Obermayer (2004)	Smoking cessation	Design: pre-post pilot study Sample: 46 smokers Setting: Colleges from the Washington DC area Recruitment: proactive Participant retention: 67% Main outcome measure: self-report – 7 Day Smoking Reconstruction Form	SMS initiation: researcher Format: daily, individually tailored SMS sent to support smoking cessation; frequency of SMS tapered around nominated quit date supplementary materials: interactive website with feedback and social support facility Duration: 6 weeks Interactivity: high	Impact outcomes: At 6 weeks point, 43% of participants had made at least one 24-hour attempt to quit, and 22% had quit based on a 7-day criterion. Process outcomes: moderately high use and acceptance of program. Satisfaction with program differed between quitters ($M = 4.3$) and non-quitters ($M = 3.2$) ($p<0.01$) Calculated effect size: NA Outcome overview: within group, positive change
Hurling (2007)	Physical activity	Design: RCT Sample: 77 healthy adults Setting: Bedfordshire, United Kingdom Recruitment: proactive Participant retention: 100% Main outcome measure: not given objective measure – accelerometer	SMS initiation: researcher Format: tailored SMS offering solutions for perceived barriers and schedule reminders for weekly physical activity Supplementary materials: email and interactive website with feedback facility; wrist accelerometers for self-monitoring Duration: 9 weeks Interactivity: moderate	Impact outcomes: At 9 weeks, the intervention group showed significantly more moderate-intensity physical activity than the control group ($p=0.02$). Average increase in the intervention group for moderate-intensity physical activity was 2 hours, 18 minutes per week (accelerometer data). Process outcomes: SMS-specific outcomes not reported. Website use was high ($M=2.9$ log-ons per week). Calculated effect size: 0.82 (moderate-intensity physical activity) Outcome overview: between group, significant, positive change in physical activity

Study	Behavior	Research design and participants	Intervention	Intervention effects
Jao (2007)	Anti-obesity behavior modification	Design: pre-post design Sample: 927: healthy adults Setting: Korean public health clinics Recruitment; active Participant retention: 47% Main outcome measure: objective measure – scales and stadiometer	SMS initiation: researcher Format: weekly, untailored behavior change SMS for nutrition and exercise Supplementary materials initial consult with dietitian, weekly brochures mailed to participants, free access to dumbbells and pedometers Duration: 12 weeks Interactivity: moderate	Impact outcomes: At 12 weeks, there were mean reductions in weight (1.6 kg, $p<0.001$), waist circumference (4.3 cm, $p<0.001$) and BMI (0.6 kg/m^2, $p<0.001$) in those who completed the 12-week program. Process outcomes: 71% of participants who completed the 12 week program thought it was effective. More than half of originally recruited participants did not complete the program. Calculated effect size: NA Outcome overview: within group, significant, positive change in weight reduction
Kirsty (2009)	Increase physical activity in type 1 adolescents	Design: RCT Sample: 78 Type 1 adolescents Setting: New Zealand Recruitment: Proactive Participant retention: 95% Main outcome measure: Step count measurement using pedometer and self-reported physical activity.	SMS initiation: Researcher Format: Weekly motivational text messaging and reminder to wear pedometer. Duration: 12 weeks. Interactivity: moderate	Impact outcomes: At 12 weeks, mean daily step count reduced by 840 (95% CI −1,947 to 266) in the control group and by 22 (−1,407 to 1,364) in the intervention group ($P = 0.4$). Process outcomes: Mean self-reported moderate or vigorous physical activity increased by 38.5 min/week in the control group and by 48.4 in the intervention group ($P = 0.9$). Calculated effect size: NA Outcome overview: Text messaging and pedometers as motivational tools did not increase physical activity.

Study	Behavior	Research design and participants	Intervention	Intervention effects
Kevin Patrick (2009)	Weight loss	Design: RCT Sample: 65 Setting: USA Recruitment: Proactive Participant retention: not given Main outcome measure: not given	SMS initiation: Researcher Format: SMS – two to five times daily. Supplementary materials: Monthly printed materials Duration: 4 months Interactivity: high	Impact outcomes: At the end of 4 months, the intervention group (n = 33) lost more weight than the comparison group (−1.97 kg difference, 95% CI −0.34 to −3.60 kg, *P* = .02) after adjusting for sex and age. Intervention participants' adjusted average weight loss was 2.88 kg (3.16%). Process Outcome: At the end of the study, 22 of 24 (92%) intervention participants stated that they would recommend the intervention for weight control to friends and family. Calculated effect size: Outcome overview: Text messages might prove to be a productive channel of communication to promote behaviors that support weight loss in overweight adults.
Mihail Cocosila (2009)	Adherence to Vitamin C pills (Out patient adherence to medication)	Design: RCT Sample: 102 subjects Setting: Canada Recruitment: Online, advertisements Participant retention: 99/102 Main outcome measure: Self-reported adherence on vitamins taken.	SMS initiation: Researcher Format: daily, reminding and reinforcing message. Supplementary materials: Nil Duration: 4 weeks Interactivity: High	Impact outcomes: There was a non-significant difference between the two groups at endpoint: an average difference of 0.8 between the number of pills missed in the last week of the trial (2.5 out of 7 in the intervention and 3.3 out of 7 in the control group) with a power of 0.54. Process Outcome: increase in compliance by 246% in the intervention group.
Irja Haapala (2009)	Weight Loss	Design: RCT Sample: 124 Setting: Finland Recruitment: Proactive Participant retention: not given Main outcome measure: not given	SMS initiation: Researcher Format: Supplementary materials: Duration: 12 months Interactivity: High	Impact outcomes: Process Outcome: Calculated effect size: Outcome overview:

1.15 Context and significance of the research

Based on the literature (Fjeldsoe 2009) mentioned earlier, a number of studies have used cell phone SMS on both preventive health behaviour (smoking cessation, physical activity and anti-obesity behaviour modification) and clinical care self-management (diabetes, asthma, hypertension) and have demonstrated significant improvement. Among these, four studies have implemented theory-based interventions and achieved significant improvement using an intervention strategy employing text messaging. Studies have shown that customised text messages can be tailored to an individual's stage of motivation to help change un-healthy behaviour and have shown that personally tailored messages are more effective for health behaviour change than untailored messages (Trevena 2006; Ryan 2002).

A recent meta-analysis on print-tailored interventions (Schwarzer 1992) suggests that tailoring interventions to behavioural intervention is more effective than generic interventions that were not tailored to an individual's stage of motivation. The TTM is the combination of both behavioural theory and stage based model that has already been successfully used in smoking cessation, physical activity, obesity and hypertension management. However, no study has been reported combining the two methodologies: cell phone text message services (SMS/information technology) and behavioural and stage based theory (TTM) for motivating and reinforcing healthy lifestyle practices for the prevention of T2DM.

Hence it is proposed to use this strategy for the primary prevention of T2DM. Key original aspects of the project are designed to correct the following shortcomings in existing knowledge:

- None of the studies available to date used the TTM model for primary prevention of T2DM.

- No studies available to date have used tailored messages to motivate subjects for primary prevention of T2DM.

- There is no study available to date to deliver tailor-made messages according to TTM stage of the participants.

METHODS AND MATERIALS

2.1 Objective

The aim of the analyses was to study the impact of transtheoretical model (TTM) - based tailored text messages to motivate the participants to follow healthy lifestyle advice for primary prevention of T2D.

2.2 Study design

This was a randomised, controlled, parallel group, prospective 2 year study in men with IGT. The study design and protocol was approved by the Ethics Review Committee of the India Diabetes Research Foundation. An independent safety committee assessed study progress with unmasked data at 6-monthly intervals. All participants gave written informed consent. Participants' physicians were informed of their patient's participation in the trial.

2.3 Methodology

The study was experimental and prospective in nature with 2 groups, control (standard LSM advice) and intervention (individually tailored healthy lifestyle advice using mobile phone messaging). Pre test and Post test design was used.

2.4 Participants

This study was conducted in the industrial work force in various public and private sector production units in Chennai, Tamil Nadu and Visakhapatnam, Andhra Pradesh, India. The employees were selected such that they would be expected to be able to continue for the full tenure of the study. Participants were selected for screening if they fulfilled all the following criteria: age 35 - 55 years, non-diabetic

subjects, 1st degree relative with T2D and body mass index $\geq$ 23 kg/m^2, persons who own a mobile phone and ability to use mobile phone. The participants were excluded if they had any serious illness, were unable to read text messages, were unwilling to participate in a prospective study or were without formal school education.

2.5 Sample size

Assuming a cumulative incidence of 30% for diabetes over 2 years (in our previous Indian study, with similar eligibility criteria (Ramachandran 2006), the incidence was 55% over 3 years), at 5% significance, with 80% power, 214 subjects were required in each group to show a 40% reduction in progression to diabetes. In a systematic review and meta-analysis, Gillies et al. had shown that, randomised controlled trials across diverse countries and populations using lifestyle interventions aimed at promoting physical activity, healthy diet practices and weight loss by personal contact can successfully reduce the incidence of T2D progression by 30% - 60% in those with IGT (Gillies 2007). We assumed that short message service (SMS) would be less effective than personal contact. We aimed to recruit 514 subjects (257 in each group) to allow for 20% drop out.

2.6 Screening

In order to recruit participants with IGT, 14 private and public sector organisations with large number of employees (>500) were identified. The study protocol was clearly explained to the occupational health officers and administrative authorities. With the consent of the employer, the screening was conducted to identify the employees falling within the inclusion and exclusion criteria. Screening, recruitment and randomisation are explained in the flowchart given below (Fig 2.1). Approximately 12,000 employees were informed about the diabetes screening programme, of which 8741 participated were tested using the 2hr post 75g oral

glucose load capillary blood glucose method. 2744 (31.4%) were diagnosed with IGT, 1832 (64%) were requested to have a 2nd oral glucose tolerance test (OGTT) within a week to confirm the status of pre-diabetes. 912 (36%) participants were excluded for the 2nd OGTT due to their blood glucose being in the range 7.8 - 8.8 mmol/L which previously, in Indian Diabetes Prevention Programme (IDPP) 1 & 2 (Ramachandran 2006: 2009) studies was frequently found to be associated with normal glucose tolerance (NGT) on subsequent testing.

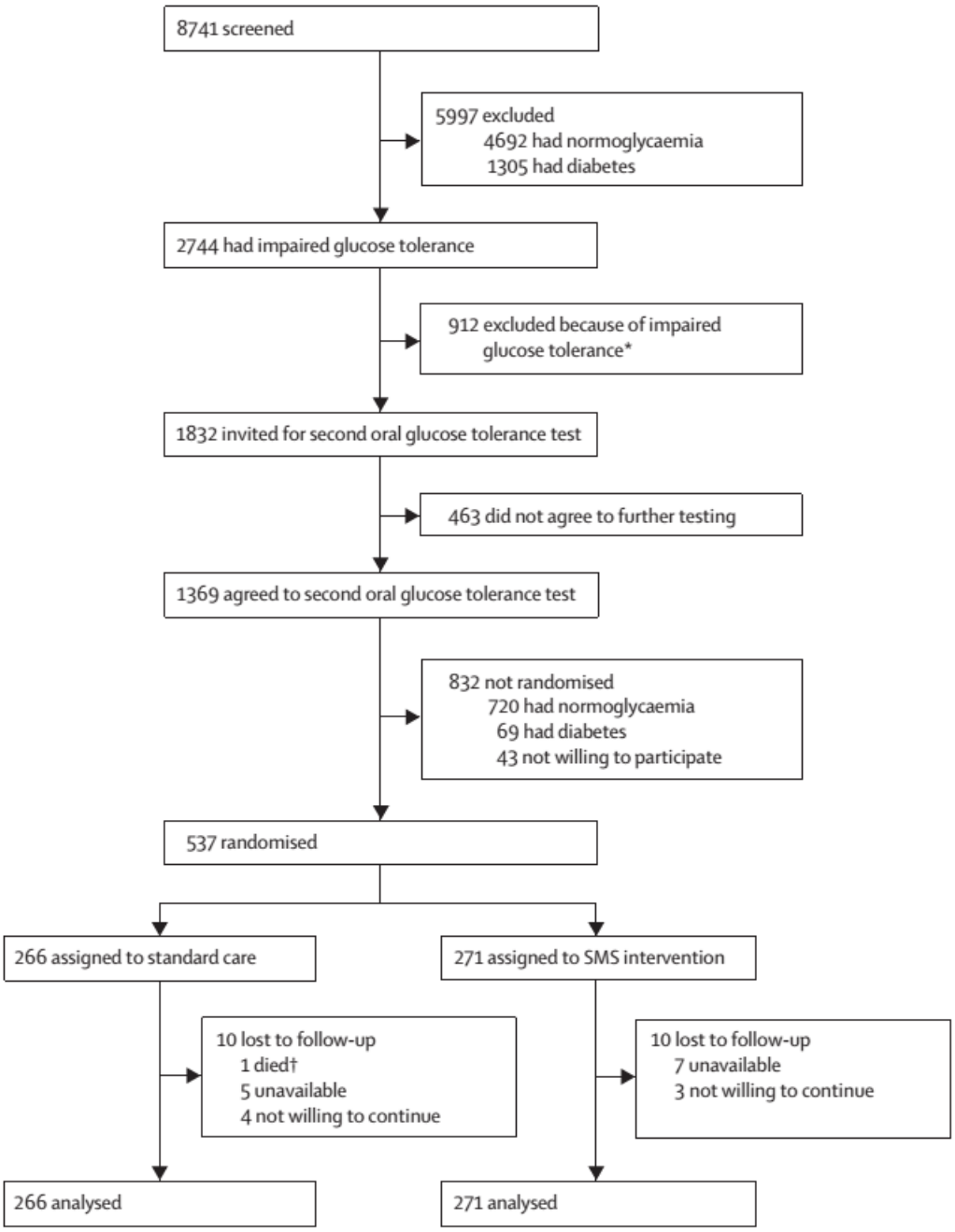
2.7 Recruitment

A 3 sample OGTT was conducted for 1832 (64%) participants, 580 (42.4%) participants were diagnosed with persistent IGT, among which 43 participants were not willing to participate in the diabetes prevention programme for various reasons (needle phobia, quantity of blood and not interested in a 2 year prospective study). Glycaemic diagnosis was based on the WHO diagnostic criteria (Report of a WHO Consultation 1999). Persons with normoglycaemia (FPG < 6.1 mmol/L, 2h post glucose (PG) < 7.7 mmol/L) or diabetes (FPG $\geq$ 7.0 mmol/L and/or 2h PG $\geq$ 11.1 mmol/L) were excluded. 537 subjects with confirmed IGT (2h PG 7.7 - < 11.1 mmol/L) were recruited in the study

2.8 Randomisation

A total of 537 subjects were randomised into two groups control (n=266) or intervention (n=271). Computer generated pseudo random numbers produced by MATLAB random number generator (Marsaglia 1991) with its default settings were used to recruit the study subjects. The screening, randomisation and follow up details are given in figure 2.1.

Figure 2.1: Figure showing screening, recruitment and follow-up details of the participants



2.9 Study procedure

Following recruitment, the subjects were reviewed every 6 months for 2 years. Information recorded at each visit is shown in Table 2.1. At baseline, participants randomised to Group 1 (control), were given standard care advice on LSM and were given general advice every 6 months follow up, for 2 years. Participants randomised to Group 2 (intervention) were sent TTM-tailored, motivating text messages on improving physical activity and healthy dietary habits. The frequency, type and timing to receive the text messages were decided according to subjects' preference. The table 2.1 shows the data collected from baseline to the end of the study.

Table 2.1 : Information recorded at each visit is shown

	Baseline	6 months	12 months	18 months	24 months
Informed consent	X				
Questionnaires' [a]					
Demographic	X				
Clinical History	X	X	X	X	X
General Health Awareness	X		X		X
Quality of life	X	X	X	X	X
Trans theoretical model assessment	X	X	X	X	X
Text messaging acceptability [b]		X	X	X	X
Anthropometric [a]					
Height (Cm)	X	X	X	X	X
Weight (Kg)	X	X	X	X	X
Waist circumference (Cm)	X	X	X	X	X
Body fat (%)	X	X	X	X	X
Blood pressure (mmHg)	X	X	X	X	X
Clinical measurements [a]					
3 sampling OGTT	X		X		X
2 hr post glucose load		X		X	
HbA1c	X		X		X
Lipid profile	X		X		X
Insulin estimations	X				X
Gamma glutamyl transferase	X				X
Alanine transaminase	X				X

a: for individuals who progressed to diabetes (confirmed by 3 sample OGTT), data recorded at that schedule time point was considered as the final values for that participant and complete clinical measurements were recorded. b: only for intervention group.

2.10 Ethics approval

Before obtaining written informed consent, all participants enrolled in the study had clearly explained to them the aim and procedures involved in the study. It was explained that participation in this prospective diabetes study would involve collecting details through questionnaires of personal information, blood sample collection for biochemical investigations, assessment on general health and diabetes, quality of life assessment, present physical activity and diet practices profile. The benefits of participation in this trial, including chances for prevention of diabetes through personalized lifestyle education, individualized motivation through SMS, periodical review of lifestyle practices, anthropometric and biochemical investigations were also explained.

The study protocol titled “The role of information technology in the primary prevention of T2D” was approved by the Ethics Committee of the India Diabetes Research Foundation, Chennai, India. The trial, NCT00819455 was registered in the clinical trials.gov.in

2.11 Lifestyle intervention

Although the study was conducted in two different states of the country, the participants’ lifestyles were similar with regard to diet and physical activity practices (for confirmation, see subsequent analyses).

During recruitment, all participants were educated on the causes, effects, symptoms, treatment, and management of diabetes, they were also educated on the possibility of preventing or delaying the onset of T2D. The participants’ queries regarding diet and physical activity were answered and beliefs regarding diabetes were also clarified. The participants were randomly allocated into control (standard

lifestyle advice only at baseline) and intervention (individually tailored TTM based text messages for two years) group (Ramachandran 2013).

The standard lifestyle advice followed a holistic approach, taking the following key healthy lifestyle factors into consideration, was explained by the nutritionist: what are the healthy and unhealthy food products, foods to be avoided or limited, the benefits of vegetables and fruits; the ill effects of sweets, sugars and carbonated drinks were also explained. The amount of oil to be consumed by a family based on their family size was also explained. Their daily nutrient intake was assessed by 24h recall method. Based on the self-reported diet practices, all subjects were given an individualized written diet chart to achieve the desired goals. These goals were to reduce portion size (total calories) and, to avoid simple sugars and refined carbohydrates, reduce total fat intake, restrict use of saturated fat, include more fibre-rich food-(e.g., whole grains, legumes, vegetables, and fruits). Subjects who had been following these healthy diet practices were encouraged to continue the same and changes were recommended if there was a need to change their diet habit. The details of the diet prescription is given in table 2.2

Participants were educated on the benefits of physical activity. The physical activity advice was intended to be simple and easy to follow and was tailored to the participant's present occupational activity level into consideration. In sedentary subjects, the recommendations were to initiate or enhance aerobic exercise like walking, cycling, and jogging in sedentary subjects. Brisk walk for minimum 30 minutes per day (or equivalent) on all days, or at least five days a week; walk 3 – 4 km in 30 min at least 5 days a week; cycle 6 -7 Km in 30 min at least 5 days a week. If the participant's occupation involved strenuous work or if participants were already engaged in walking or cycling for more than 30 min a day the advice given was to continue the same. Sedentary participants were advised to initiate physical activity,

participants with light activity were advised to increase physical activity and participants were asked to maintain the level in order to achieve and maintain ideal bodyweight and glycemic improvement. The prescribed physical activity and diet recommendations are shown in table 2.2 and were similar to those used in our previous diabetes prevention trial (Ramachandran 2006).

Table 2.2: Dietary advice and physical activity recommendations to the participants

Dietary advice

The dietary recommendations were individualized to balance food intake and physical activity and to maintain appropriate body weight. The advice includes:

a. Avoidance of simple sugars and refined carbohydrates
b. Reduce total fat intake (not to exceed 20 g/day)
c. Restrict use of saturated fat
d. Include more fibre-rich food – whole grains, legumes, vegetables and fruits.

Adherence

Scores are given based on the following

Poor: Not followed the advice on > 5 days/week (non-adherent)

Fair: Occasional deviation following 2-4 days/week (adherent)

Good: Strictly following diet advice >5 days/week (adherent)

Dietary adherence (no sugar, ↓ refined carbohydrates, ↓ calories, ↑ fibre, ↓ fat) was evaluated every 6 months. Scores were given at that time to assess the adherence

Physical activity recommendation:

a. To enhance aerobic exercise like walking, cycling and jogging in sedentary subjects
b. Brisk walk for a minimum of 30 min/day (or equivalent), as a realistic goal which has proven efficacy
c. Walking 3 – 4 km in half an hour at least five days a week
d. Cycling 6 -7 km in half an hour
e. If occupation involves strenuous work, no specific advice

Adherence

During each visit improvement in activities were assessed

Poor: No activity or <150 min (Non-adherent)

Fair : 150 – 250 minutes (adherent)

Good: >250 minutes or if the occupation involved strenuous work (Adherent)

In addition to these standard lifestyle recommendations at baseline, no further advice was given to both control and intervention group participants through telephone or personal contact, except in response to specific queries from participants. Participants in the intervention group alone received TTM stage-based tailored SMS on diet and physical activity at regular intervals. These messages contained information about the benefits of healthy lifestyle, cues to initiate behavioral change, and strategies to avoid relapse and remain motivated to continue physical activity and healthy dietary habits. Samples of SMS are given table 2.3 (Ramachandran 2013). In both study groups, the transtheoretical model stage of each participant was assessed by questionnaire at baseline and during review visits.

Table 2.3 shows examples of mobile phone text message reminders for physical activity and diet, tailored according to transtheoretical model stages

TTM stages	Physical activity SMS	Diet SMS
Precontemplation	• Physical activity helps to maintain normal blood sugar and blood pressure. • Active life makes you live longer.	• Eat healthy, be healthy and be happy. • Regular eating pattern helps to maintain normal blood sugar.
Contemplation	• Moderate physical activity keeps you healthy • Desk-bound job? Take a short walk to relax your body and mind.	• Avoid snacks while watching TV, you may overeat. • Neither fast nor feast, have a balanced diet
Preparation	• Use stairs instead of a life • Get off the bus one or two stops ahead and walk to the destination	• Increase fibre rich foods, fruits and vegetables and whole cereals. • Make your place colourful by adding lots of vegetables.
Action	• All you need is 30 minutes of moderate physical activity on most days of the week. • A good exercise can keep your mind stress free.	• Take fruits as a whole and not as a juice • Fruits are delicious and nutritious, include them as a part of your diet.
Maintenance	• Were there many missed walks this month? No worries start today. • Are you stressed out! Stress increases blood sugar. Go for a walk and relax.	• Skipping breakfast will make you overeat at lunch. • Hope you had a healthy week.

The SMS content at any time was based on the TTM stages of change, based on the following principles. As described previously (Sections 1.12.1, 1.12.2) the TTM model explains how people vary in terms of motivational readiness to quit unhealthy behavior and move through specific stages for behavior change. The TTM consists of 5 stages of change (precontemplation, contemplation, preparation, action and maintenance) developed by Prochaska and DiClemente (Prochaska 1983). Each stage is unique in its characteristics: precontemplation, no awareness of the benefits of healthy lifestyle, hence no change, contemplation, aware but has not taken any realistic steps toward the goal, intend to change in the next six month, preparation, working out strategies to meet the desired goal, action, practicing healthy lifestyle for less than six months duration, maintenance, following healthy lifestyle more than six months and working to prevent relapse to the previous stage. According to this model, people use both cognition and behavioural strategies and techniques to progress through these 5 stages which are described as process of change. The first 3 stages involve changes at the cognitive level, including:

- Create awareness and increase awareness
- Awareness raising of the ill effects associated with unhealthy lifestyle
- Impact of unhealthy lifestyle on his or her family, friends and at the community level
- Benefits of healthy lifestyle
- Increase awareness of opportunities for physical activity and healthy diet practices

The fourth and fifth stages involve changes at the behavioral level including:

- to adhere to healthy lifestyle even when stressed out or tired or when there are opportunities to slip down
- To associate with people who aspire to achieve similar goals
- To reward or reinforce themselves when achieving desired goals
- To stay more active and follow healthy diet
- To avoid cues for unhealthy lifestyle and to leave reminders for healthy lifestyle

An overview of the type (diet or physical activity), content, frequency, time of delivery of the SMS was explained to participants in the intervention group and they were also informed about the mechanisms of delivery of SMS.

2.12 Tools used

Four questionnaires were used in this study:

1. The Transtheoretical Model Inventory to assess the study subjects' TTM stages in relation to physical activity and diet habits,
2. The short message service acceptability questionnaire
3. The World Health Organization-Quality of life BREF questionnaire (WHOQOL Group 1998),
4. General health and diabetes awareness questionnaire (Murugesan 2007)

Questionnaires 1 and 2 were developed by the investigator specifically for the present study. Questionnaires 3 and 4 are standardised questionnaires. The descriptions of tools used are given below.

2.12.1 The Transtheoretical model stage inventory

An essential aspect of this work was to define a subject's TTM stage with respect to physical activity and dietary habits. In order to assess the effect of tailored text messages in transitions in TTM stages in the intervention group and to compare them with the control group, the researcher constructed a project-specific TTM inventory. This comprises a questionnaire of 20 items, 10 items each to determine the participant's TTM stage in relation to dietary habits and physical activity practices.

A two stage pilot study was conducted in the development of this tool. The first stage of the pilot study was conducted among 10 members of the study team. Modifications were made based on the feedback and suggestions from the team members about the items. The second stage pilot study was conducted among 40 non-diabetic volunteers and further modifications were made based on the response from these non-diabetic volunteers. The present version of the questionnaire was approved to be used in this study after 'face validation' (comprising an expert assessment of a tool, viewed as covering the concept it proposed to measure) by two health psychologists.

It is well-documented that the TTM model is a widely applied behavioral theory in health research, however there is no sufficient data to show the usage of Prochaska's originally developed TTM questionnaire in health research. Hence the researcher developed the questionnaire specifically to meet the study objective. According to Prochaska's stages of change model, duration of lifestyle practices

(number of months) is the criterion to decide the subject's TTM stage on a particular behavior. The questionnaire was developed taking duration of diet and physical activity practices into consideration but although duration of an individual's habits is the major criteria for stage assessment, additional questions were posed to ascertain their actual diet and physical activity practices. These additional questions are called lie scales. Lie scales are the set of items or questions included in a psychological evaluation to ascertain whether or not the respondent has been truthful in answering the other items in the questionnaire. The responses to the questions are yes or no format. Question numbers 1, 3, 6 and 9 assesses the participants TTM stage, and the other 6 questions are lie scales. Similar questionnaire was constructed to assess the TTM diet stages of change. The TTM physical activity and diet inventories are given as appendix 1 and 2, and scoring keys are given as appendix 3 and 4.

2.12.2 SMS Acceptability Questionnaire:

A project-specific SMS acceptability questionnaire comprising 8 items was developed by the researcher. A similar SMS acceptability questionnaire was used in a clinic-based study in which the utility of SMS was tested to reinforce Asian Indian diabetes patients visiting their hospital clinic to adhere to prescription recommendations (Ananth Samith Shetty 2011). The study showed that frequent communication via SMS was acceptable to diabetic patients and it helped to improve their health outcomes. The questionnaire used in the present study was a modified version with questions to suit the study's specific needs. This modified questionnaire was intended to help measure the acceptability, frequency, difficulty in understanding, advantage, preferred time and problems due to the SMS. One question invites participant's suggestions to improve. The response to the questions was "Yes or No", and each correct response was given a score of 1. The SMS acceptability questionnaire was used at each follow up to assess the acceptance of

the SMS received by the intervention group. The assessment also helped the researcher to make changes in the frequency, timing and type of SMS (diet or physical activity) delivered to the subjects. A copy of the questionnaire is included in the appendices, appendix number 5.

2.12.3 WHOQOL-BREF Questionnaire

The WHOQOL-100 (World Health Organisation Quality Of Life-100) allows detailed assessment of each individual facet relating to quality of life. However, the original WHOQOL-100 was felt as too lengthy for practical use. The WHOQOL-BREF -BREF Questionnaire is an abbreviated version of the larger WHOQOL-100 data set. The WHOQOL-BREF field trial version has therefore been developed to provide a short-form quality of life assessment that looks at domain level (physical, psychological, social and environmental) profiles, using data from the pilot WHOQOL assessment and all available data were from the field trial version of the WHOQOL-100. Twenty International field testing centres situated within eighteen countries were included simultaneously, in an attempt to develop a quality of life assessment that would be applicable across various cultures (The WHOQOL Group, 1994a). India is one among those eighteen countries. In India, the pilot version of the WHOQOL and field trial of the WHOQOL-100 was carried out in Chennai city where the present study was conducted and in New Delhi, in the Northern part of India. This pilot and field study showed that the WHOQOL-BREF questionnaire was suitable for use in this present study population.

The WHOQOL-BREF contains a total of 26 questions. To provide a broad and comprehensive assessment, one item from each of the 24 facets contained in the WHOQOL-100 was included. In addition, two items to assess the subject's overall quality of life and his perception towards general health were included.

The WHOQOL-BREF is available in 19 different languages and is available in the regional language Tamil also. The questionnaire may be self-administered if the participant has sufficient ability to answer, otherwise completion of the questionnaire is interviewer-assisted. The participants recruited in the present study were required to have received minimum school education and moreover the questionnaire was also distributed in the regional language, therefore the questionnaire was answered by the subjects themselves without any help from the researcher. Each questionnaire was accompanied by detailed instructions. A time frame of two weeks was given to recall the events related to the questions were given for the questions to be answered.

2.12.3.1 Scoring of the WHOQOL-BREF

The WHOQOL-BREF gives the quality of life profile of the participant based on four domain scores. The four domains (physical, psychological, social and environmental quality of life) scores indicate an individual's perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote higher quality of life). The mean score of items within each domain is used to calculate the domain score.

The details of four domains, 24 facets and the questions assessing each domain are given in the table 2.4. The questionnaire and scoring key are enclosed in appendices, appendix number 6.

Table 2.4 Showing the description of the WHOQOL-BREF questionnaire

DOMAIN AND QUESTION NUMBERS	FACETS INCORPORATED WITHIN DOMAINS
1. **Physical health** (Q3, Q4, Q10, Q15, Q16, Q17, Q18)	Activities of daily living Dependence on medicinal substances and medical aids Energy and fatigue Mobility Pain and discomfort Sleep and rest Work capacity
2. **Psychological** (Q5, Q6, Q7, Q11, Q19, Q26)	Bodily image and appearance Negative feelings Positive feelings Self-esteem Spirituality / Religion / Personal beliefs Thinking, learning, memory and concentration
3. **Social relationships** (Q20, Q21, Q22)	Personal relationships Social support Sexual activity
4. **Environmental** (Q8, Q9, Q12, Q13, Q14, Q23, Q24, Q25)	Financial resources Freedom, physical safety and security Home environment Opportunities for acquiring new information and skills Participation in and opportunities for recreation / leisure activities Physical environment (pollution / noise / traffic / climate) Transport

2.12.4 General Health and Diabetes Awareness Questionnaire

The original version of this questionnaire, the awareness on general health and diabetes awareness questionnaire, was developed by Prof. Ramachandran and team (Murugesan 2007) under the WHO programme “Diabetes Action Now”, at the WHO collaborating centre for diabetes, Chennai, Tamil Nadu, India. The objective of the “Diabetes Act Now” program was to assess the awareness level of general health and diabetes among general public and diabetic patients. The study was conducted in 2004, with a total of 3681 persons interviewed. A team of workers trained in psycho-social survey was involved in the pilot study and final phase of validating the questionnaire. This questionnaire is used to assess the subjects’ knowledge about physical activity and healthy dietary habits in maintaining good health and prevention and management of diabetes. The questionnaire is divided into general health (questions on assessing types of good physical activity, and knowledge on healthy and unhealthy diet). Diabetes awareness is assessed with questions on causes, effects, symptoms, complications and prevention of diabetes. For the present study, we have modified the original version of the questionnaire for easy comprehension and brevity to assist completion of the questionnaire while applying it to the present study population.

The questionnaire comprises three sections, applicable both to the general public and diabetic patients: 1) section A. The demographic profile of the participant, 2) section B. Awareness on general health and 3) section C. Diabetes awareness assessment. In the present study, the demographic profile was collected as part of the study details. In section B, questions on knowledge on general health included awareness regarding healthy physical activity, physical activity time each day for a healthy person, knowledge regarding types of food considered healthy and unhealthy, and methods of improving health and knowledge on reliable sources on

health information. Section C. assesses the awareness level regarding diabetes. The questions concerned signs and symptoms of diabetes, causes of diabetes, effects (complications) of diabetes in the long term, knowledge regarding the development of complications and possible ways of preventing diabetes.

2.12.4.1 Scoring the General Health and Diabetes Awareness Questionnaire

In modifying the questionnaire for the present study, the scoring was also slightly altered to accommodate the changes made in the questionnaire from its original version. Each question has multiple choices to answers hence the scores differ for each question mentioned above. Each correct answer was given a score of one and the scores were added to indicate the subject's level of awareness on a particular question. The maximum scores for each question were; healthy physical activity (score 9), physical activity time in a day for a healthy person (score 1), healthy and unhealthy food (score 15), and methods of improving health (score 9), and source of reliable information (score = 1), the sum of these score quantifies the participants awareness level on general health. The maximum possible score was 35. The distribution of scores on diabetes awareness was as follows: signs and symptoms of diabetes (score 7), causes of diabetes (score 7), effects (complications) of diabetes in the long term (score 4), knowledge regarding the development of complications (score 1) and possible ways of preventing diabetes (score 4). The sum of these scores quantifies the awareness level of the participant regarding diabetes. The maximum possible score was 23.

The questionnaire and scoring key are enclosed in the appendices. Appendix number 7.

2.13 Development of SMS

As outlined above in section 2.11, concerning the interventions that participants received, the short messages service (SMS) was used as an intervention tool and was developed on the basis of information collected from various sources. The researcher collected information from the patient educators and nutritionists of Dr. A. Ramachandran's Diabetes Hospitals, from their day to day work experience with the patients regarding patients' awareness, knowledge, attitude, diet and physical activity practice profile and the beliefs regarding the disease. Similar information was collected also from the research team who had already been involved in the previous IDPP trials in which standard care advice was one of the intervention principles. The information was pooled, rephrased or modified as short messages to meet the study objectives. The SMS were broadly categorized into diet and physical activity messages. General health and smoking messages were also included.

2.13.1 Characteristics of SMS

At baseline, both control and intervention group received personalized education and motivation on healthy lifestyle principles, and individualized written diet and physical activity recommendations were given to participants based on their present lifestyle. These recommendations were similar to those used in our previous diabetes prevention trial (Ramachandran 2006). In addition to standard care advice participants in the intervention group received healthy lifestyle SMS messages based on behavioural theory: the transtheoretical model stages of change. The SMS delivered to the participants were short (less than 160 characters), with simple words and easy to understand. The SMS content was on the causes, effects and prevention of diabetes and other associated lifestyle diseases. SMS messages on

benefits of healthy lifestyle, pros and cons of changing and not changing the behavior, cues to initiate or start physical activity and overcome unhealthy dietary habits were delivered. Strategies to avoid or overcome relapse to the previous unhealthy behavior and to sustain healthy lifestyle were also included. In general, the objective of the SMS was to create awareness, assist, guide and support the individual to change unhealthy lifestyle and motivate to move across stages by providing various cues and strategies to follow and remain motivated throughout the life.

2.13.2 Concepts in the development of SMS

As mentioned earlier in section 1.12.2, TTM is the underlying behavioral theory in this intervention. It consists of 4 core constructs; the “stages of change”, “process of change”, “decisional balance”, and “self-efficacy”. The stages of change (precontemplation, contemplation, preparation, action and maintenance stage) is the main construct of this model which explains the steps involved in progressing to the desired behavior. Although, stages of change is the major construct of this model which demonstrates the benefit of SMS through change in subject’s progression and regression between stages, the process of change explains how people change their behavior (DiClemente 1982; Prochaska 1983; Prochaska 1992; Velicer 1998). The detailed description of the processes of change is shown in table 2.5. Briefly, processes of change includes ten cognitive (i.e. involving thinking) and behavioral (i.e. involving action) strategies that can help subjects’ to make positive changes and maintain them.

The cognitive processes include:

1. Consciousness raising
2. Dramatic relief
3. Environmental re-evaluation
4. Self-re-evaluation
5. Social liberation.

The behavioral processes of change are:

1. Counter conditioning
2. Helping relationships
3. Reinforcement management
4. Self-liberation
5. Stimulus control.

These strategies state that different strategies (process) are most effective and relevant at different stages of change when people move from one stage to the other. For example, counter-conditioning and stimulus control can really help people in the action and maintenance stages, but these processes are not helpful for someone who is in the first three stages.

2.13.3 Validation of the SMS

The investigator compiled the messages as a comprehensive list of short statements (the SMS) which incorporate five cognitive and five behavioral strategies of processes of changes. The messages covered both physical activity and dietary dimensions. The SMS were validated by the following validation process method. The SMS were analyzed by 5 expert psychologists, specialized in health psychology, psychological training assessments and psychometrics. In the first step, the experts were asked to rate each message for its loading as a cognitive or behavioral component. The ratings were collected based on concurrence for each item, the higher the concurrence the more valid the message. In the next step, the experts were asked to classify the SMS in any one of the ten process strategies based on the principle that the processes differ when people move from one stage to the other. For example, cognitive processes of change (consciousness raising, dramatic relief, environmental re-evaluation, social liberation and self-re-evaluation) are relevant for the first three stages and behavioural processes (reinforcement management, helping relationship, counter conditioning, stimulus control and self-liberation) are relevant for the action and maintenance stage. Messages were written taking the characteristics of the above variables into consideration.

Table 2.5 Showing the processes for each stage of change

STAGES	PROCESSES OF CHANGE	EXPLANATION
Precontmeplation To Contemplation	Consciousness raising	Increased awareness of causes, consequences, and cues to overcome the problem; increasing information about self and the unhealthy behaviour
	Dramatic relief	Experiencing and releasing feelings about the possible consequences of the behavior; using feelings to help motivate change
	Environmental re-evaluation	Cognitive and affective assessments of how the presence or a absence of the behavior affects one's social environment; becoming aware that one can serve as a positive or negative role model to others
	Social liberation	Recognizing changes in the environment or social changes that influence personal change
Contemplation To Preparation	Self-re-evaluation	Cognitive and affective assessments of the subject's self-image with and without behaviour in order to change how one thinks about oneself in relation to the behaviour
Preparation To Action	Self-liberation	Recognizing choices related to available actions and making a commitment to change a behaviour
Action To Maintenance	Reinforcement management	Applying consequences in the form of rewards to oneself for making changes
	Helping relationships	Seeking and accepting support from others in the form of caring, trust, acceptance, and openness
	Counter conditioning	Learning new and healthier alternative behaviours to substitute for the unhealthy behaviour
	Stimulus control	Avoiding or removing environmental cues for unhealthy behaviour and adding cues for healthier alternatives

In the context of the study design and procedures described in detail in this section, a series of analyses were undertaken. These are described in the following sections as standalone study reports, each dedicated to the topic of a particular analysis. The analysis described in the following section, Section 3, has already appeared in print (Ramachandran et al 2013).

EFFICACY OF MOBILE PHONE MESSAGING IN PREVENTION OF TYPE 2 DIABETES BY LIFESTYLE CHANGE IN MEN AT HIGH RISK – A RANDOMIZED CLINICAL TRIAL IN INDIA

3.1 Background and objectives

Primary prevention of T2D is needed to curb its rising trend globally, particularly in low and middle income countries (Unwin IDF Diabetes Atlas 5th ed. 2011). Several randomised controlled trials have shown that LSM can reduce the conversion from prediabetes to diabetes by 50 percent (Pan 1997; Ramachandran 2006; Tuomilehto 2001; Knowler 2002; Kosaka 2005; Gillies 2007). Such programmes are labour intensive and have not been implemented widely, even in high income countries. Text messaging (short message service, SMS) by mobile phone is an alternative means of delivery of educational advice and motivation to achieve LSM (Holtz 2012; Shetty 2011; Quinn 2011; Fjeldsoe 2009; Vodopivec-Jamsek 2012).

Much has been written about the potential of mobile technology in disease management (De Jongh 2012). If successful, the tool is potentially scalable as mobile phones are widely used by people of a broad range of all socioeconomic status even in low and middle income countries (De Jongh 2012; Cole-Lewis 2010). Mobile phone messages are inexpensive and have the advantage of instant transmission. The number of messages sent globally tripled between 2007 and 2010 (http://www.worldbank.org/en/). However, strong supportive data are lacking for a successful role in disease management. A Cochrane review had included only 4 randomised controlled trials involving in total 182 participants to provide a scientific evidence base for mobile phone messaging in management of any long-term conditions, and none of the studies was in diabetes (De-Jongh 2012). Other reviews

have highlighted the paucity of randomised trials (Free 2013; Bell 2012) although some data on disease management is emerging (Quinn 2011; Zolfaghari 2012; Lester 2010) and a role of SMS in improving adherence to antiretroviral therapy has been established for people with HIV infection (Free 2011). There is little evidence for mobile phone messaging in disease prevention (Cole-Lewis 2010) although a role as an aid in smoking cessation has been demonstrated (Marsaglia 1991).

We designed this trial to test the hypothesis that SMS encouraging lifestyle change, sent via mobile phones, would reduce incident diabetes in people with IGT compared with a control group receiving standard lifestyle advice. Potential cardiovascular benefits and the acceptability of the messages to the recipients were also assessed. The study was performed in India, a country with high diabetes prevalence and widespread mobile phone ownership.

3.2 Methods

3.2.1 Trial Design

This was a prospective, parallel-design, randomized, controlled trial over 2 years comparing the effectiveness of tailored SMS with standard lifestyle advice. The study protocol was approved by the Ethical Committee of the India Diabetes Research Foundation. An independent Safety Committee assessed study progress on unblinded data at 6 monthly intervals.

3.2.2 Participants

The trial was performed in working Indian men with IGT. The men were employed in various public and private sector industrial units in South East India (Chennai, Tamil Nadu and Visakhapatnam, Andhra Pradesh) and were recruited after obtaining their informed written consent. The study was performed in the

workplace and as 96·3 percent of the employees were men, only men were included in the trial. Their jobs were classified as unskilled, skilled or clerical/executive as reported by them. Eligibility criteria for screening included: being non-diabetic (self-reported) and having no major illness, such as cancer, chronic liver or kidney disease, or conditions with cognitive impairment, severe depression or mental imbalance; absence of physical disability which would prevent regular physical activity; not recruited into another trial; age 35–55 years; ownership of a mobile phone and ability to read and understand SMS in English; positive family history of diabetes and body mass index ≥ 23·0kg/m^2.

Following screening for eligibility by questionnaire, capillary blood glucose was measured using a glucometer (Accu–Check Sensor, Roche Diagnostics, Mannheim, Germany), 2 hours after 75g oral glucose, in the participants' workplace. Amongst the subjects identified with IGT (n = 2744), those with 2 hours blood glucose values ≥8·9 mmol/l were invited for a confirmatory oral glucose tolerance test within one week. During the 2^{nd} test, venous blood samples were collected at 0, 30 and 120 minutes.

3.2.3 Interventions

At baseline, all study participants received personalized education and motivation on healthy lifestyle principles and written information on diet and physical activity. The prescribed lifestyle changes were similar to those used in our previous diabetes prevention trial in India (table 2.2) (Ramachandran 2006). Participants were advised to balance food intake and physical activity and to achieve and maintain an ideal body weight. The dietary principles were: 1) avoid simple sugars and refined carbohydrates; 2) reduce total fat intake (<20g/day); 3) restrict saturated fat; and 4) include more fibre-rich food – whole grains, legumes, vegetables and fruits. For

physical activity, participants involved in strenuous occupations and those who either walked or cycled for more than 30 minutes/day, or who already exercised regularly in other ways, were asked to continue these activities. Participants' who engaged in sedentary or light physical activity, as assessed in the initial interview, were advised to walk briskly every day for a minimum of 30 minutes. The participants' physicians were informed of their participation in the trial.

Following these lifestyle recommendations at baseline, all participants were re-assessed clinically and biochemically at six monthly intervals. No additional lifestyle information or advice was given routinely by personal or by telephonic contact after the baseline visit, except in response to specific queries from the participants. This applied to both control and intervention groups. In addition, the intervention group received text messages at frequent intervals. These SMS contained information about healthy lifestyle, the benefits of physical activity and diet, cues to initiate physical activity and healthy dietary practices, strategies to avoid relapse and to motivate to maintain physical activity and healthy dietary habits.

The SMS content at any time was based on the transtheoretical model of behavioural change (Prochaska 1997; Tuah 2011). The transtheoretical model is a stage-based behavioural change paradigm, in which individuals moving between stages in a discrete way qualitatively. People differ in their perception and action according to their stages in relation to their behaviour change. The model distinguishes five stages in adopting change: pre-contemplation, contemplation, preparation, action and maintenance. The transtheoretical model stage of each participant (control and intervention groups) was assessed by questionnaire at the baseline and review visits and the message content in the intervention group was tailored according to their present transtheoretical model stage.

A transtheoretical model stage-based SMS delivery manager website was created in partnership with the Intel Corporation. The messages were delivered by a commercial service provider (Unicel technologies, India). They contained <160 characters and there were 60-80 messages for each transtheoretical model stage, such that participants would not normally receive the same message in a 6 month period (based on their receiving 2-4 messages per week). The assumption was that the participants would move from a pre-action stage to an action stage. The timing (0500–0800h or 1700-2000h) and frequency of messages were tailored to the participants' wishes assessed at the 6 monthly visits. Examples of mobile phone message reminders for physical activity, tailored according to stage of TTM stages are shown in table 2.3. The participants were informed of the mechanisms for delivery of their text messages and were expecting them in the agreed format.

Oral glucose tolerance tests were performed at baseline, 12 and 24 months, and were assessed by World Health Organization recommendations (Report of a WHO consultation 1999). Plasma was separated within an hour for biochemical analysis. The samples were kept at -20°C for insulin assay. In order to minimize discomfort and inconvenience, at 6 and 18 months a capillary blood sample was taken at 2 hours after oral glucose was administered in the fasting state. Only if this value was ≥11·1mmol/l a formal oral glucose tolerance test performed, with venous plasma sampling in the fasting, 30 minutes and at 2 hours. Diabetes was defined by fasting plasma glucose of ≥7·0 mmol/l and/or a 2 hours oral glucose tolerance test plasma glucose of ≥11·1 mmol/l (Report of a WHO consultation 1999). The diagnosis was confirmed within one week by a second test. Subjects diagnosed with diabetes were referred to their physicians for further management.

Height was measured at baseline; weight (body mass index calculated), waist circumference, and blood pressure by sphygmomanometer (mean of two readings) were measured at each visit by standard procedures. Plasma glucose (hexokinase method, coefficient of variation <3·0 percent at 10·0 mmol/l and 20·0 mmol/l) was measured at each visit; fasting triglycerides, total cholesterol and high density lipoprotein cholesterol were measured annually using an auto analyzer with appropriate quality control. Plasma insulin was measured at fasting, 30 minutes and at 2 hours post oral glucose by chemiluminescence (ELICA, Roche diagnostics) at baseline. Insulin resistance (HOmeostasis Model Assessment of Insulin Resistance, HOMA-IR) was calculated using the formula: ([fasting insulin (mU/l) x fasting glucose (mmol/l)] / 22·5) (Matthews 1985). Insulinogenic index was calculated by dividing the increment in insulin at 30 min by glucose at 30 min during the oral glucose tolerance test (Wareham 1995).

Physical activity and dietary intake were assessed by questionnaire completed with field workers at baseline and during the 6-monthly reviews. Physical activity was quantified on a score of 7-70 (Ramachandran 2006).

The activity questionnaire was based on that used previously in South Asian Indians in an epidemiological survey in West London, U.K. (McKeigue 1991) slightly modified for the Indian environment and used previously in our diabetes prevention studies in India (Ramachandran 2006). Dietary intake was assessed by 24-hour recall method.

Information on adherence to dietary and physical activity recommendations was recorded at the 6-monthly reviews. Adherence to diet and physical activity was self-reported, based on their weekly pattern and scored as poor, fair or good (table 2.2) (Ramachandran 2006). For statistical analysis, the data were dichotomised into

non-adherent and adherent categories, as shown in table 2.2. Energy intake was calculated for individual food items using the National Institute of Nutrition (NIN) guidelines for India (Gopalan 1989).

SMS acceptability was assessed in the intervention group using a short questionnaire developed specifically for the present trial. Scoring (0 or 1) was based on the responses to questions on message content and frequency, ease of understanding, whether it was considered a disturbance and whether it was perceived as a help in improving lifestyle. The questionnaire total score was 6, with 6 being the most acceptable and 0 the least. The questionnaire also queried the preferred time of day to receive messages and invited suggestions for improvements.

Assessments were performed by 7 field staff trained in the performance of glucose tolerance tests and the biometric measurements. Training was performed by central training staff using continuous training methods previously employed in our diabetes projects in India (Ramachandran 2006). Each person had a designated role to minimise inter-individual error.

3.3 Outcomes

The primary study outcome was incident diabetes.

Secondary outcomes included: (1) body mass index (kg/m^2); (2) waist circumference (cm); (3) systolic and diastolic blood pressure (mmHg); (4) lipid profile (total and high density lipoprotein cholesterol (mmol/l) and triglycerides (mmol/l)); (5) dietary total energy intake and (6) physical activity score.

The acceptability of text messaging was assessed by questionnaire in the SMS (intervention) group.

Ancillary analysis variables were not prespecified and included HOMA-IR and insulinogenic index calculated at the baseline visit and estimates of adherence to dietary and physical activity recommendations.

3.4 Sample size

Assuming a cumulative incidence of diabetes of 30 percent over 2 years (in our previous Indian study with similar eligibility criteria (Ramachandran 2006), the incidence was 55 percent over 3 years), at 5 percent significance, with 80 percent power, 214 subjects were required in each group to show a 40 percent reduction in progression to diabetes. In a meta-analysis of behavioural modification studies (Gillies 2007) the mean reduction was 50 percent and we assumed that SMS would be less effective than personal contact. We aimed to recruit 514 subjects (257 in each group) to allow for 20 percent drop out during follow-up.

3.5 Randomization sequence generation, allocation concealment and implementation

Randomization was performed using a computer-generated random number allocation system (MATLAB 'randperm', http://www.mathworks.com/ moler/ random.pdf), based on the Marsaglia random number generator algorithm. This resulted in 266 participants in the control group and 271 in the intervention group. Randomisation was achieved by a single central investigator who was not involved in the analysis of trial data. Enrolment was performed by field workers.

3.6 Blinding

Laboratory personnel, principal and co-investigators were blinded to the participants' group assignments until the end of the study. Field staff were, by necessity, not blinded.

3.7 Statistical methods

Intention-to-treat analysis was used. The estimated cumulative incidence of T2D was computed and unadjusted Cox's regression analysis was used to compute the hazard ratio and survival curve for intervention relative to control. The number needed to treat, and 95 percent confidence interval (CI), to prevent one case of diabetes, was calculated as the inverse of the absolute risk reduction and its 95 percent CI.

To evaluate the effects of the intervention on secondary outcomes (and ancillary analysis variables), mixed-linear regression modelling with maximum likelihood parameter estimate was used for continuous variables. Skewed variables (triglycerides and physical activity score) were log transformed before analysis. Differences in the estimated marginal means between the groups with 95% CI were presented. Generalized Estimating Equation-based logistic regression analysis was used to analyze categorical outcomes (diet and physical activity adherence) with adjustment for baseline values and time. The corresponding odds ratios (95% CI) with P values are shown.

Changes were computed by subtracting final follow-up from the baseline values; for those who developed diabetes, the values at the time of diagnosis were considered as the final value. Cox's regression analysis was used to assess the impact of change in secondary outcome and ancillary analysis variables and baseline

values of 2hours glucose, HOMA-IR and insulinogenic index on incident diabetes. The statistical package SPSS, Version 19.0 (IBM statistics, USA) was used.

3.8 Role of funding sources

The United Kingdom India Education and Research Initiative (UKIERI) evaluation board assessed the outline protocol in a competitive funding process but neither UKIERI nor the World Diabetes Foundation (WDF) had any further role in the trial. The corresponding author had full access to all trial data and had final responsibility for decision to submit for publication.

3.9 Results

3.9.1 Recruitment and participant flow

Screening and recruitment occurred between August 2009 and November 2010 (figure-2.1). Following initial screening by questionnaire and capillary glucose estimations at 2 hours post oral glucose, 1369 of the 2744 eligible agreed to a second oral glucose tolerance test. Of these, 580 had persistent IGT of whom 43 did not wish to participate further. The remaining 537 agreed to be randomised.

3.9.2 Baseline data

Following randomisation, baseline characteristics were similar in the intervention and control groups (Table-3.1). The majority of workers were skilled or clerical/executive. At entry, no subject in either group was on lipid modifying treatment but 69 in each group were on hypotensive medication. Dietary energy intake, compatibility of diet with advice during the trial and the distribution of physical activity scores were similar in both groups at baseline. The response rate was 96·3

percent (n=517) at final follow up. The mean duration of follow-up was 20·2±7·0 months.

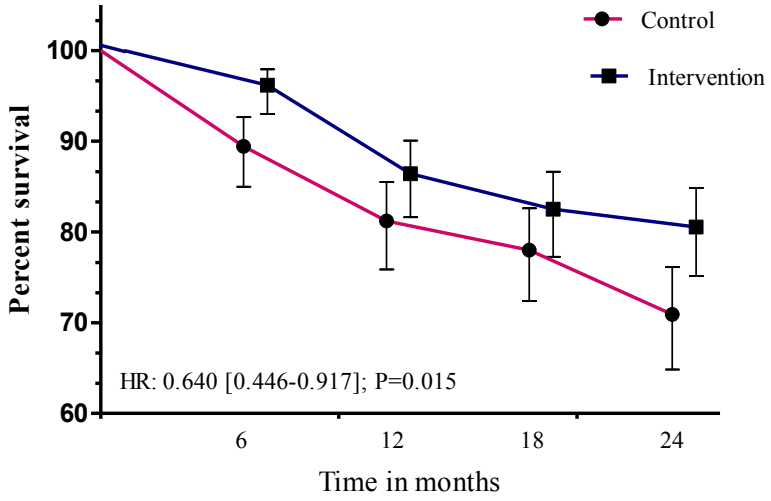
Table-3.1: Baseline characteristics of study participants

Characteristics	Control (n=266)	Intervention (n=271)
Age (years)mean ± SD	46·1±4·6	45·9±4·8
Occupation, n(%)		
Unskilled workers	11 (4·1)	9 (3·3)
Skilled	170 (63·9)	164 (60.5)
Clerical/executive	85 (32·0)	98 (36·2)
Family history of diabetes, n(%)	131 (49·2)	150 (55·4)
Body mass index (kg/m^2), mean ± SD	25·8±3·0	25·8±3·3
Waist circumference (cm), mean ± SD	92·7±7·3	92·6±7·1
Blood Pressure (mmHg), mean ± SD		
Systolic	123·4±14·3	123·1±13·6
Diastolic	80·2±8·4	80·2±8·4
Plasma glucose (mmol/l), mean ± SD		
Fasting	5·70±0·55	5·63±0·53
2 hour	8·90±0·86	8·79±0·78
Serum lipids (mmol/l), mean ± SD		
Total cholesterol	4·91±0·94	4·87±0·89
High density lipoprotein cholesterol	0·90±0·19	0·90±0·21
Triglycerides median (inter quartile range)	1·6 (1·2-2·3)	1·6 (1·1-2·1)
HOMA-IR (dimensionless), mean ± SD	3·2±1·5	3·0±1·3
$\Delta I_{30-0}/G_{30}$ (pmol/mmol) median (inter quartile range)	48·9 (27·9-78·5)	47·6 (30·0-81·7)
Dietary energy intake (kcal/24h), mean ± SD	2100·0±278·0	2121·0±296·0
Baseline diet compatible with advice during trial n (%)	136 (51·3)	141 (52·0)
Physical activity score median (inter quartile range)	36 (31-56)	36 (27-54)

3.9.3 Primary outcome and estimation

Three cases of diabetes diagnosed by treating physicians outside the trial (2 in control and 1 in intervention group) were included after the diagnosis was confirmed from medical records. Other cases were ascertained in the trial. Fifty subjects (18·5 percent) in the intervention group developed diabetes over the 2 years compared with 73 controls (27·4 percent), an absolute risk reduction of 8·9 percent. Cox proportional hazards modelling showed that the intervention reduced the incidence of diabetes during the course of the study (β=-0·447, hazard ratio 0·640 (95%CI: 0·446-0·917) p=0.015) (Figure-3.1). The number needed to treat to prevent one case of diabetes was 11 (CI: 6-55).

Figure 3.1. Survival curve



Time (months)	0	6	12	18	24
Subjects at risk (n)					
Control	266	228	215	176	187
Intervention	271	245	240	196	209
Cumulative incidence of diabetes					
Control (n)	--	27	48	56	73
Intervention (n)	--	10	35	45	50

Cox's Proportional Hazard model showing the probability of remaining free of diabetes (WHO criteria) among men stratified in the study groups; vertical bars show 95 percent CI for the cumulative probability of remaining free of diabetes

3.9.4 Secondary outcomes

At the end of follow up, repeated measures ANOVA showed no significant effect of the intervention on body mass index, waist circumference, blood pressure, serum cholesterol and triglycerides but there was a positive effect on high density lipoprotein cholesterol (0·033[95%CI: 0·011 to 0·054]) (Table-3.2). Total dietary energy consumption was lower in the intervention group compared to controls (-43.7 [95%CI: -65·5 to -22·0]), whereas physical activity scores did not differ (Table 3.2).

Table 3.2: End of follow-up secondary outcomes and adherence to dietary intake and physical activity recommendations in each study group †

	Control N=266 Mean (SD)	**Intervention N=271 Mean (SD)**	**Difference in mean change (95% CI)**
Anthropometry			
Body mass index (kg/m^2)	25·0 (5·4)	25·0 (5·5)	-0·05 (-0·46 to 0·37)
Waist circumference (cm)	92·6 (7·7)	92·6 (7·9)	0·04 (-0·56 to 0·64)
Blood pressure (mmHg)			
Systolic	121·4 (13·0)	121·4 (13·0)	0·04 (-0·96 to 1·03)
Diastolic	78·8 (7·4)	78·7 (7·3)	-0·07 (-0·64 to 0·49)
Serum lipids (mmol/l)			
Total cholesterol	4·9 (0·9)	4·9 (0·9)	0·010 (-0·08 to 0·10)
HDL cholesterol	0·9 (0·2)	1·0 (0·2)	0·033 (0·11 to 0·54)
Triglycerides§	1·60 (1·22-2·27)	1·52 (1·16-2·09)	-0·080 (- 0·17 to -0·06)
Self reported			
dietary energy intake (kcal)	2042·5 (269·8)	1998·7 (295·4)	-43·7 (-65·5 to -22·0)
Physical activity (Score)§	38·0 (25·0 – 54·0)	39·0 (27·0-54·0)	-1·0 (- 2·0 to 0)
Difference in percentage adherence (OR [95% CI]; P value)*	--		
Diet	--	1·357 (1·008-1·826)	P=0·0442
Physical activity		1·110 (0·779-1·573)	P=0·572

† Mixed-linear regression analysis, taking into account visit and intervention, to generate end of follow-up estimated marginal means and difference in mean change (95% CI)

§log-transformed: back-transformed and their corresponding median (inter-quartile range was shown)

*: Repeated measures logistic regression analysis taking using each visit and intervention to compare the adherence to diet and physical activity between groups

3.9.5 Ancillary analyses

At the end of follow-up, the proportion of participants adherent to diet was higher (OR: 1·36 (95%CI 1·01-1·83); P=0·04) but adherence to physical activity recommendations did not differ in the two groups.

Significant predictors of incident diabetes were: increased body mass index, lower dietary compliance, higher baseline HOMA-IR and 120 minutes plasma glucose and lower baseline insulinogenic index. On entry of these variables in a single Cox proportional hazard model, the significance of each variable was sustained (Table-3.3). Randomisation group was not included in this model due to co-linearity with dietary compliance.

Table-3.3: Independent, significant change in secondary outcome variables (including dietary adherence) and baseline variable predictors of incident diabetes[†]

Variables	HR [95%CI]	P Value
Min 120 OGTT glucose (baseline) (mmol/l)	1·728 (1·406-2·122)	<0·0001
HOMA-IR (baseline) (no dimensions)	1·175 (1·075-1·285)	<0·0001
Insulinogenic index (baseline) (pmol/mmol)	0·993 (0·988-0·998)	0·006
Change in BMI, (Kg/m^2)	1·329 (1·151-1·535)	<0·0001
Change in dietary adherence	0·482 (0·327-0·710)	<0·0001

[†]significant predictors of incident diabetes were entered in a single Cox proportional hazards model; randomised group was not included as a variable in the model due to co-linearity with 'Change in dietary adherence'.

3.9.6 Acceptability of text messages

The frequency of text messaging at baseline was decided individually in line with participants' wishes and initially a median of 18 messages per month (range 8-24) were requested. At final follow-up, the median requested was 12 (range 8-16). Analysis of the acceptability questionnaire data indicated that messages were generally welcomed and the median questionnaire score out of 6 was 5·0 (range 3-6). No more than 3 percent of people at any review stated that receiving the SMS was disturbing them.

3.10 Harms

One subject in the control group died suddenly at the end of the first year. There were no other serious adverse events.

3.11 Discussion

3.11.1 Interpretation

This trial is the first to demonstrate benefit from SMS as a tool in the prevention of T2D. The magnitude of reduction in progression to diabetes is similar to that reported previously in India using personal contact methods (Ramachandran 2006). The text messages were generally well accepted. The proof of principle has therefore been established that text messaging can be an effective and acceptable tool for LSM to reduce diabetes incidence.

The people included in the trial were at especially high risk, having 2 hour glucose levels ≥8.9 mmol/l in their first oral glucose tolerance test. Their high rate of progression to diabetes (27.4 percent in 2 years) was similar to that reported in our earlier Indian diabetes prevention programme (Ramachandran 2006). Using SMS,

we had aimed to induce dietary change and to increase physical activity. The text messaging was associated with reduced dietary energy consumption on recall. However, reported physical activity and body weight were similar in the intervention and control groups. This apparent independence of glycaemic benefit from body weight reduction or increase in physical activity has been observed in some previous conventional diabetes prevention programmes (Pan 1997; Ramachandran 2006). Physical activity in the present study was assessed only by questionnaire and small changes may be missed using this methodology. In our previous diabetes prevention study in India (Ramachandran 2006), which used personal contact methods of delivery of the lifestyle programme, we did observe increased physical activity in lifestyle practice groups using similar assessment methodology. As with previous studies however, the physiological basis for benefit is unclear.

Cox's regression analysis indicated that baseline 120 minutes plasma glucose and HOMA-IR were predictive of incident diabetes, and that higher beta cell function was protective. Irrespective of study group, increased body mass index was associated with high incidence, compatible with some of the previous conventional diabetes prevention studies (Tuomilehto 2001; Knowler 2002).

The glycaemic benefits from text messaging were observed early (at 6 months), indicating that their impact was rapid. High density lipoprotein cholesterol levels were slightly but significantly higher. Weight loss and increased physical activity are two determinants of circulating high density lipoprotein levels but in our study we cannot be sure of the mechanism. Elevated high density lipoprotein concentrations have been reported previously in conventional diabetes prevention studies (Tuomilehto 2001; Ratner 2005).

3.12 Limitations

Our study has limitations. Firstly, the trial included only working men, as the employees of the industrial organizations which agreed to participate were mostly (96·3 percent) men. Women's responses and reactions to text messages might differ from those of men but we would have recruited insufficient women to assess gender effects. Hence, the efficacy and acceptability of SMS in women, and amongst other groups of men, need to be addressed in future studies. Secondly, the setting was an urban population in India. The application of text messaging to other populations needs study. Finally although our methodology attempted to minimise bias, the field workers were by necessity not blinded and we cannot exclude the possibility of bias, however unlikely, at this level.

We have used the transtheoretical model in our study as the basis for the LSM strategy. Although this model has a considerable evidence base (Prochaska 1997) it is not uniformly accepted (Tuah 2011) and we cannot be sure of its importance in this trial as other methods were not studied.

3.13 Generalizability

As SMS is potentially scalable and likely to be of relatively low-cost, its use in larger prevention programmes warrants evaluation. This is especially as the benefits of preventing or delaying diabetes onset have remained with the participants for up to 20 years (Li 2008; DPP Research Group 2009; Lindstrom 2013). They extend to other cardiovascular risk factors and possibly to cardiovascular events (McKeigue 1991). The challenge has been to find a way to implement behaviour modification programmes in a cost effective manner. Personal contact methods are likely to remain expensive and innovative solutions have been sought for primary care and

workplace settings (Ruggiero 2012). Text messaging is now part of an alternative strategy.

3.14 Overall evidence and conclusion

This study has shown that SMS is an effective and acceptable communication tool for educating and motivating people at high-risk of diabetes in order to reduce diabetes incidence.

IMPACT OF TRANSTHEORETICAL MODEL BASED TAILORED TEXT MESSAGES IN BEHAVIORAL CHANGE TO PREVENT TYPE 2 DIABETES

4.1 Introduction

Health is a major global concern. The interest in health research is increasing globally. Healthy lifestyles are collective patterns of behavior based on choices available to people according to their living conditions. Such lifestyles can be viewed as consistent health-related behaviours like smoking, alcoholism and substance abuse that are enabled or constrained by a person's social situation and living conditions (Galani 2007; Tzormpatzakis 2007). There is substantial evidence to show that diseases such as diabetes, coronary artery disease (CAD), cardiovascular disease (CVD), ischemic stroke, hypertension and obesity are lifestyle diseases that are increasing rapidly and are now becoming major causes of morbidity and mortality. All these diseases are associated with unhealthy behaviour such as physical inactivity, high calorie diet and smoking habits (Ramachandran 2008; Ramachandran 2004). This poses an immense economic burden in developed and developing countries. Medicines alone cannot cure chronic diseases and a person's lifestyle practices can either cause or prevent such conditions. Consequently, health has become an achievement – a goal people are expected to work for. Typically they accomplish this through positive healthy lifestyle practices, which include avoidance of smoking, healthy eating habits, moderating alcohol use, exercising, and similar health-promoting behaviours. Conversely, unhealthy practices like tobacco use, high fat diets, excessive alcohol consumption, lack of exercise, and similar negative health habits are underlying causal factors for many chronic diseases. Interventions to change these unhealthy behaviors have been

found to be effective in reducing the risk of developing chronic diseases (Ramachandran 2010; Ratner 2005)

Diabetes is considered the fourth or fifth leading cause of death worldwide (IDF Diabetes Atlas 6th edition 2013). In India, the prevalence of diabetes has increased over the last 2 decades and is steadily rising, with contributions from genetic predisposition, advancing age and increasing body mass index (Ramachandran 2011). The high mortality rate associated with diabetes is attributed to the increased rates of micro and macro-vascular complications. Cardiovascular disease is the leading cause of morbidity and mortality among patients with diabetes. Among people with T2D, the rate of non-compliance with treatment and preventive measures is high (Cramer 2004; Fischer 2010) and this appears to be the major cause of increased morbidity and mortality in people with T2D (Asche 2011; Hansen 2010).

Although there have been a few attempts in primary prevention of type 1 diabetes (Skyler 2013), the results have not been encouraging. Hence, attention has focussed on primary prevention of T2D and it is primary prevention of T2D that is discussed here.

Primary prevention is defined as the prevention of a disease by controlling modifiable risk factors through population prevention programmes. The non-modifiable risk factors for T2D are age, sex, family history, genetic predisposition, history of gestational diabetes (GDM), and ethnicity. The modifiable risk factors include overweight and obesity, sedentary lifestyle, unhealthy diet, previously identified glucose intolerance, adverse intrauterine environment, alcohol consumption, and tobacco smoking. It is these modifiable risk factors that are targeted by primary prevention strategies (Ramachandran 2012).

4.2 Feasibility and effectiveness of primary prevention strategies in type 2 diabetes

Diabetes prevention programmes conducted in different parts of the world in various ethnic and racial populations have conclusively shown that T2D is a preventable disease. By controlling the adverse effects of environmental risk factors either by LSM (Tuomilehto 2001; Ramachandran 2006) or with pharmacologic agents (Knowler 2002) the development of diabetes in people at high risk for the disease can be prevented or delayed considerably. Persons with IGT and/or IFG or women with a history of GDM have high risk for diabetes and have been studied in prospective randomized controlled trials that include the Swedish Malmo study, the Chinese Da-Qing study, the Finnish Diabetes Prevention Study, the American Diabetes Prevention Program (DPP), the Indian Diabetes Prevention Programme (IDPP) and the Japanese Diabetes Prevention Study (JDPS) (Da-Qing 1999; Tuomilehto 2001; Knowler 2002; Ramachandran 2006; Kosaka 2005). All these prevention programmes have LSM (improved physical activity and eating healthy diet) as one of the intervention goals for prevention of diabetes and a few (IDPP1, DPP) have also used metformin in the primary prevention of T2D.

All the above landmark diabetes prevention trials showed that LSM was effective in at-risk subjects of varied ethnicity, in men and women, and in overweight (Tuomilehto 2001; Knowler 2002) or lean subjects (Pan 1997; Ramachandran 2006; Kosaka 2005). It has been further demonstrated that LSM is effective in different racial populations (Swedish and Finnish white Europeans, African Americans and Asian Americans in the DPP study and Asians in the Chinese Da-Qing study, Indians in the IDPP-1 study). Healthy diet, regular physical exercise, and avoidance of smoking and excess alcohol consumption are emphasized. The principles of LSM are sustained physical activity of 30 to 40 minutes on all or a minimum of 5 days a

week and restricted calorie intake, with reduction of refined carbohydrate and fat content and inclusion of food fibre (Lindstrom 2010). Reduction of weight in obese persons by intensive practice of LSM has shown beneficial effects (DPP, DPS).

Overall, the published information of the effects of lifestyle changes is encouraging, with at least a 28% reduction in progression from IGT to T2D. However, it seems unlikely that significant lifestyle changes will be achieved even in developed countries, or maintained long-term (Lindstrom 2006; Knowler 2009; Li 2008) in otherwise healthy individuals, given the background of unrestrained and relatively unhealthy behavioural lifestyle choices enjoyed by the rest of the community. In this setting, it is important to consider the possibility of pharmacological intervention.

4.3 Behavioural theories and behavioral intervention

Interventions to change lifestyle have been effective in preventing diabetes as shown by all the major landmark diabetes prevention programmes (Ramachandran 2011). The evolution of behavioural intervention began with behavioural counselling in a clinic or a primary care centre on a one-to-one basis. Later it was developed to deal with an individual's problem through telephone contacts. Now it is further developed as personalised mailing through internet e-mail, delivering self-help guides or materials. Recently, the concept has been focused on an individual's' more specific problem like physical inactivity and eating disorder, thereby offering health education and behaviour change support to overcome these problematic behaviours.

In recent years there has been a considerable awareness and increase in the need for theory-driven research in the process of health behaviour change, especially researches related to promotion of physical activity and healthy eating habits with

promising results. A review (Whitlock 2002) has referred to six commonly cited behaviour change theories used in the primary care centres, which include: 1) the health belief model; 2) the theory of reasoned action or theory of planned behaviour; 3) stages of change or transtheoretical model; 4) social cognitive theory or social learning theory; 5) community organization or building and 6) social marketing in behavioural counselling intervention. These theories seek to explain the biological, cognitive, behavioural and psychosocial/environmental determinants of health-related behaviours. They also define intervention methods to bring changes in an individual's knowledge, attitudes, motivation, self-confidence, skills, and social supports which are required for healthy behaviour and maintenance of such behaviour (Elder 1999).

4.4 Stage theories and stage transitions

In recent years there has been increased attention given to stage theories in health promotion and research. The rationale behind the application of stage theories is that for people passing through an ordered set of behaviour qualitatively at different stages (Weinstein 1998) in the course of their progression, to decide on, to start and to maintain health-related behaviours is both perceptual and cognitive process. This is relevant to the design of the intervention that is envisaged (Brug 2005). The major outcomes in stage theories are stage transitions rather than behaviour itself, because prior to the intervention no positive behaviour is performed by the individual: each stage is qualitatively different in its characteristics and different factors are responsible for the desired behaviour progressing through different stages (Weinstein 1998). This important feature differentiates stage-based theories from cognitive-based theories, such as the theory of planned behaviour (Ajzen 1991), according to which behaviour change is a continuous process. By contrast, according to stage theories, progression through stages (behaviour change)

takes place when there is a change in perception and cognition, which means behaviour change is not a continuous process and different information is appropriate at different stages of this change process (Heckhausen 1988), Therefore it is important to identify the stage of the individual seeking intervention, in order to promote progression and to understand relapse to a previous stage in the process of change.

4.5 Transtheoretical model

The Transtheoretical Model (TTM) is a behavioural theory which is widely applied in health research interventions in the unhealthy lifestyle of individuals. The TTM has been described as an integrative and comprehensive model that is derived from key theories in psychotherapy (Prochaska 1999). The original research application of this theory was in negative addictive behaviour like smoking later in substance abuse. Research application of the theory demonstrated how self-changers had changed successfully without professional intervention (Prochaska 1999; Prochaska 1983). The four core constructs of the model are the “stages of change,” “process of change,” “decisional balance,” and “self-efficacy” (Prochaska 1997). The stage of change (SOC) is the main construct of this model and demonstrates the ‘steps involved’ in progressing to the desired behaviour (Velicer 1998). The process of change explains ‘how’ individuals change their behaviour. It includes cognitive, affective, evaluative and behavioural strategies that an individual may adopt to modify the problem behaviour.

Over the last two decades there has been a substantial increase in the application of TTM in behaviour modification studies. Most of these studies have been behavioural intervention-oriented and highlighted the significance of different

constructs from the TTM in helping sedentary individuals to be more active (Dunn 1999; Steptoe 1999).

4.6 Transtheoretical model; Stages of change

The TTM stage of change paradigm represents a sequential construct and assumes that individuals will go through a series of five stages in adopting a healthy behaviour or quitting an unhealthy one (Prochaska 1992; Prochaska 1997). These five stages are termed: *pre-contemplation, contemplation, preparation, action and maintenance* and they refer sequentially to achieving a desired behaviour or quitting an unhealthy one. Formal definitions of each of these stages have been developed (Prochaska 1992; Prochaska 1997a; Prochaska 1997b). These are central to the present work and are quoted here in full:

4.6.1 Pre-Contemplation is the stage in which an individual has no intent to change behaviour in the near future, usually defined as the next six months. Individuals at this stage may not be informed or may lack information about the consequences of their behaviour, or they have attempted to change their behaviour and failed and, therefore, are demoralized in their ability to change their behaviour. These people are often characterized as resistant or unmotivated and tend to avoid information, discussion, or thought with regard to the targeted health behaviour (Prochaska 1992; Prochaska 1997b).

4.6.2 Contemplation is the stage where individuals openly state their intent to change within the next six months. The individuals have increased awareness of the benefits of changing but are still considering the cost involved in changing the behaviour. These people are seriously undecided to change and are stuck at this stage for a longer period of time. They are also known as contemplators or

procrastinators and are often not ready for traditional action-oriented programs (Prochaska 1992; Prochaska 1997b).

4.6.3 Preparation is the stage in which the person intends to take steps to change, usually occurring within the next 30 days. These individuals have attempted some important action in the past and most often have a plan of action, for example attending health education classes and talking to the counsellor. These are the people who are best suited for action-oriented programs (Prochaska 1997b). However, the individuals have not met the criteria for effective action and can be considered as at the early stirrings of the action stage (Prochaska 1992).

4.6.4 Action stage refers to when people made overt modifications in their lifestyles within the past six months. Individuals must meet the criteria agreed by professionals to reduce the risk of a disease (Prochaska 1997b). Action is defined as the most explicit behavioural transformation and needs considerable commitment of time and energy. For example, a successful change of addictive behaviour means achieving a specific criterion such as abstinence (Prochaska 1997b).

4.6.5 Maintenance is the stage in which individuals work to avoid relapse and are most often less tempted to deteriorate as they increasingly become confident and able to continue their changes (Prochaska 1997b). Conventionally, maintenance was viewed as a static stage, whereas it is actually a continuation and not merely an absence of change. Thus, the characteristics of this stage are stabilizing behaviour change and avoiding relapse (Prochaska 1992).

Exceptionally, a sixth stage, the termination stage, is added, which applies to some behaviours, particularly addictions such as smoking and alcohol abuse, where the individuals have no temptation and total self-efficacy. These people will not return

to their old unhealthy habit as a coping mechanism in spite of high emotional pressure such as being depressed, lonely or stressed (Prochaska 1997b).

In addition, the researchers have conceptualized "relapse" (recycling) which is not a stage in itself but rather the "return from action or maintenance to an earlier stage."(Rollnick 1999)

All the previous diabetes prevention programmes (Pan 1997; Tuomilehto 2001; Knowler 2002; Ramachandran 2006; Kosaka 2005)) have involved multiple personal contacts with the participants by the healthcare professionals. The trials' successes have resulted from the investigators' ability to motivate participants through individualised input, which is highly labour intensive. Therefore a new system for the management of chronic disease risk that allows patients to control their healthcare in real-life situations is required. Information technology (IT) such as telephone contact, Internet-and e-mail-delivered interventions or a mobile phone short-message service have been found to be effective alternatives, which could reduce the demand of personal behavioural counselling programmes, improve patient compliance and reduce costs (Hellerstedt 1997; Tate 2001; Tate 2003; Hurling 2007). The high rate of mobile phone use in India renders this as an appropriate medium for this country. Based on the literature (Fjeldsoe 2009; Krishna 2008) it is found that emerging technology such as mobile phone text messaging services offer another inexpensive, economical and well accepted method to send and receive text messages containing healthy lifestyle reminders.

4.7 Behaviour change interventions facilitated by mobile phone text messaging services

It is a continuous task for the health care professionals to offer long term, sustained health improvements to their patients in the managements of chronic disease such as T2DM. Quality and effective treatment requires repeated contacts between the health care provider and the patients (Institute of Medicine, Committee on quality of health care in America 2001; Wagner 1996). Finding a new way to improve the contact between these is again an important issue. Intervention strategies using automated telephone message systems have been demonstrated to improve knowledge among participants and achieve better health improvements (Krishna 2002; Piette 2000; Piette 2001). Telephone-based interventions have had favourable outcomes among low socioeconomic groups and ethnic minorities (Albright 2005).

In a chronic disease such as T2DM, to monitor and maintain the blood glucose levels and other physiological conditions of the patient requires regular monitoring through self-care behaviours. Internet e-mail technology-based interventions are playing a vital role in the quality of diabetes care (Balas 2004). The use of a cell phone text messaging service is a step towards educating patients on self-monitoring and management and also to receiving feedback about their present health condition for better management and feedback between scheduled clinic visits. The application of a short message service (SMS) in behavioural research is new. However there are number of robust studies demonstrating the use of SMS to remind subjects about medical appointments (Bos 2005; Downer 2005; Milne 2006; Vilella 2004; Cohen 2008), to co-ordinate medical staff (Sherry 2002), to deliver medical test results (Pal 2003; Tomnay 2005; Menon-Johansson 2006) and to monitor patient side effects following treatment (Weaver 2007).

The SMS intervention strategy may be particularly useful among people who use mobile phones as their main source of communication. This medium allows the researcher, personally to send and receive short messages (maximum 160 characters) to any place, at any time or in any setting immediately according to the individual convenience. This is a quantifiable interaction between the researcher and the subject that can be monitored, measured and compared for effectiveness of the intervention. The accessibility of SMS communication may also make it more effective than other telephone or print-based interventions (Sherry 2002; Pal 2003; Tomnay 2005; Menon-Johansson 2006; Weaver 2007; Atun 2006).

Most studies to date were conducted on clinical care interventions to improve the compliance level of the patient; only very few studies concentrated on preventive health behaviour using SMS as a reminder tool (Fjeldsoe 2009). In a review (Krishna 2008) on diabetes self-management care via cell phone, some studies showed cell phones and text messaging facilitated regular treatment advice and support between clinic visits. In other studies, cell phones and text messaging proved to be good tools to deliver regular alerts and reminders to achieve desired goals. Nine of the 10 studies that used cell phone technology for education, care and support of the patient showed significant decreases in HbA1c values among those who received care and support through cell phone.

Since mobile phone SMS technology is highly accessible to all socio economic groups it acts as a primary source of information or as a knowledge delivery medium for health behaviour change interventions among people with poor health or unhealthy lifestyle. As more and more people start using cell phones, SMS technology may be found to be a more cost effective mode of communication than conventional telephone communication and may be combined with other methods to educate and support people needing constant motivation (Gimenez Perez 2002;

Leong KC 2006). Studies involving nurse short messaging services (Kim 2007) and also Yoo et al., (Yoo 2009) indicated that SMS was associated with improved HbA1C and 2-h post glucose levels for 12 weeks in people with T2DM. For instance, the commercial internet physical activity programme 'Active Living Every Day (ALED) PA' is a behaviour change programme based on transtheoretical model (TTM) and social cognitive theory (Carr 2008) and has been effective in improving cardio metabolic risk factors in sedentary adults.

Hence, it is hypothesised that TTM based LSM programme (or 'behavioural change programme') focused on persons who are at high risk for developing T2DM, using mobile phone text messaging services as a motivating tool will change their lifestyle. Secondly, it is intended to assess the acceptance of text messages as a motivating tool to change one's life style.

4.8 Context and significance of the research

Based on the literature mentioned earlier (Fjeldsoe 2009), number of studies have used cell phone SMS on both preventive health behaviour (smoking cessation, physical activity and anti-obesity behaviour modification) and clinical care (diabetes self-management, asthma self-management and hypertension self-management) and have demonstrated significant improvement. Among these, four studies have implemented theory-based interventions and achieved significant improvement using an intervention strategy employing text messaging. Studies have shown that text messages can be tailored to an individual's stage of motivation to help change un-healthy behaviour and have shown that personally tailored messages are more effective for health behaviour change than untailored messages (Trevena 2006; Ryan 2002).

A recent meta-analysis on print-tailored interventions (Noar 2007) suggests that tailoring interventions to behavioural intervention is more effective than generic interventions that were not tailored to an individual's stage of motivation. The TTM is the combination of both behavioural theory and stage based model that has already been successfully used in smoking cessation, physical activity, obesity and hypertension management. However, no study has been reported combining the two methodologies: cell phone text message services (SMS/information technology) and behavioural and stage based theory (TTM) for motivating and reinforcing healthy lifestyle practices for the prevention of T2DM. Hence it is proposed to use this strategy for the primary prevention of T2DM. Key aspects of the project are designed to address the following shortcomings in existing knowledge:

- None of the studies available to date used the TTM model for primary prevention of T2DM.
- No studies have used tailored messages to motivate subjects for primary prevention of T2DM.
- No study has used both the strategies (TTM and SMS) together to motivate participants to adhere to lifestyle practices.

4.9 Methods and Materials

4.9.1 Aim

The aim of this study was to assess the effect of transtheoretical model based tailored SMS on adherence to healthy lifestyle advice by the participants in a diabetes prevention study. This was an experimental, randomized controlled prospective 2 year study in men with IGT. The research design was approved by the institutional ethics committee. The study consisted of two groups, control (standard

care advice) and intervention (healthy lifestyle advice using mobile phone text messaging services). The analysis primarily concerned lifestyle before and after the intervention

4.9.2 Participants

This study was conducted in the work force in various public and private sector production units in Chennai, Tamil Nadu and Visakhapatnam, Andhra Pradesh, India. The employees were selected such that they would be available for the full tenure of the study. Participants were selected for screening if they fulfilled all the following criteria: Age 35 - 55 years, non-diabetic subjects, 1st degree relative with T2D and / or Body mass index $\geq$ 23 kg/m^2, persons who own a mobile phone and ability to use mobile phone. The participants were excluded if they had any serious illness, could not read text messages, were unwilling to participate in a prospective study and lacked formal school education. The total number of study participants recruited was 537 (266 in control and 271 in intervention). The sample size calculation, screening, recruitment and randomization method is described in section 2 and 3.

4.9.3 Study procedure

Following recruitment, the subjects were reviewed every 6 months for 2 years. At baseline, all participants received standard care advice about healthy lifestyle principles, and individualised written information about diet and physical activity. No additional lifestyle information or advice was routinely given by personal contact after the baseline visit either to the control or to the intervention groups, except in response to specific queries from participants. In addition to the standard care advice at baseline, the intervention group was sent TTM-tailored, motivating

SMS on improving physical activity and healthy dietary habits. The frequency, type and timing to receive the text messages were decided according to subjects' preference. The details of the study procedure are explained in figure 2.1 given in section 2.

4.9.4 The intervention

During recruitment all the study participants were personally educated on healthy lifestyle to modify food intake and increase physical activity. A personalised diet chart was prescribed to reduce total calorie and fat intake (<20 g/day), restrict saturated fat and include more fibre rich food such as whole grains, dhals, legumes, vegetables and fruits. Physical activity recommendations were made according to their regular physical activity practices. Participants with strenuous work, who had work-oriented physical activity, or who had already been walking or cycling for more than 30 min/day or exercising regularly were advised to continue the same. Participants who were involved in a sedentary job or light physical activity were advised to start brisk walking for a minimum of 30 min/day for at least 5 days a week. Both the diet and physical activity recommendations were similar to those employed in the IDPP 1 and Indian diabetes prevention programme 2 (Ramachandran 2006; Ramachandran 2009). These recommendations were found to be acceptable to the population under study.

4.9.5 Tools used

The following two questionnaires were developed by the investigator specifically for the present study:

1) Transtheoretical Model Inventory to assess the study subjects TTM stages in relation to physical activity and diet habits

2) Text Messages Acceptability Questionnaire

4.9.5.1 Transtheoretical Model stage inventory

As described in section 2, the Transtheoretical Model Inventory was an essential aspect of this work and was designed to define a subject's TTM stage with respect to physical activity and dietary habits. To assess the effect of tailored text messages in transitions in TTM stages in the intervention group and to compare them with the control group, the researcher constructed a project-specific TTM inventory to assess the 5 TTM stages. This comprised a questionnaire of 20 items, 10 items each to determine the participant's TTM stage in relation to dietary habits and physical activity practices, respectively.

A two stage pilot study was conducted in the development of this tool. The first stage of the pilot study was conducted among 10 members of the study team. Modifications were made based on the feedback and suggestion from the team members about the items. The questionnaire was further refined based on the responses of 40 non-diabetic volunteers to the questionnaire after the first revision based on the first stage responses. A copy of the questionnaire is enclosed as appendix 2.

4.9.5.2 SMS Acceptability questionnaire

As described in detail in section 2, a project-specific SMS acceptability questionnaire was developed, comprising 8 items. This questionnaire quantified the acceptability, frequency, difficulty in understanding, advantage, preferred time and problems due to the SMS. One question invited participants' suggestions to improve. The text message service acceptability questionnaire was used at every follow up to assess the acceptance of the text messages received by the intervention group. A copy of the questionnaire is included as appendix 3.

4.10 Analysis

4.10.1 Objectives

In this study the transtheoretical model stages of change is the key element to assess the subjects' change in behavioral practices (diet and physical activity practices). Hence it is aimed to analyse the changes in the distribution of study subjects' at different transtheoretical model stages in both diet and physical activity practices from the time of recruitment among the control and intervention groups. In addition to stage transition it is aimed to assess the subject's mean calorie consumption at different TTM stages and differences in consumption of macronutrients between the two study groups at baseline and at follow up. The objectives were, therefore:

- To compare the baseline distribution of subjects in different TTM stages in diet and physical activity practices.
- To compare the baseline distribution in TTM stages of diet and physical activity practices between the two study groups.
- To compare the changes in TTM stages with respect to the diet and physical activity practices in two years during the follow up.
- To analyse the difference in total calorie consumption in the study groups with respect to the TTM stages.
- To analyse the difference in consumption of carbohydrates, protein, fat and fibre among control and intervention groups at baseline and at follow up.

4.10.2 Statistical procedures

Frequency histograms were derived for the baseline distributions of subjects at different TTM stages in diet and physical activity practices. Number and percentage are used to show the distribution at baseline and follow up. Mean and standard deviation were summary measures for total calorie consumption in control and intervention groups in different TTM stages at baseline and follow up. Independent sample 't' test was used to identify significant differences in calorie consumption between the two study groups and paired "t" test was used to analyse significant changes within each group. One way ANOVA was used to analyse the difference in consumption of macronutrients in relation to the five stages of the TTM across follow up. Univariate logistic regression analysis was used to analyse the protective effect of lifestyle goals in relation to incident T2D.

4.10.3 Results

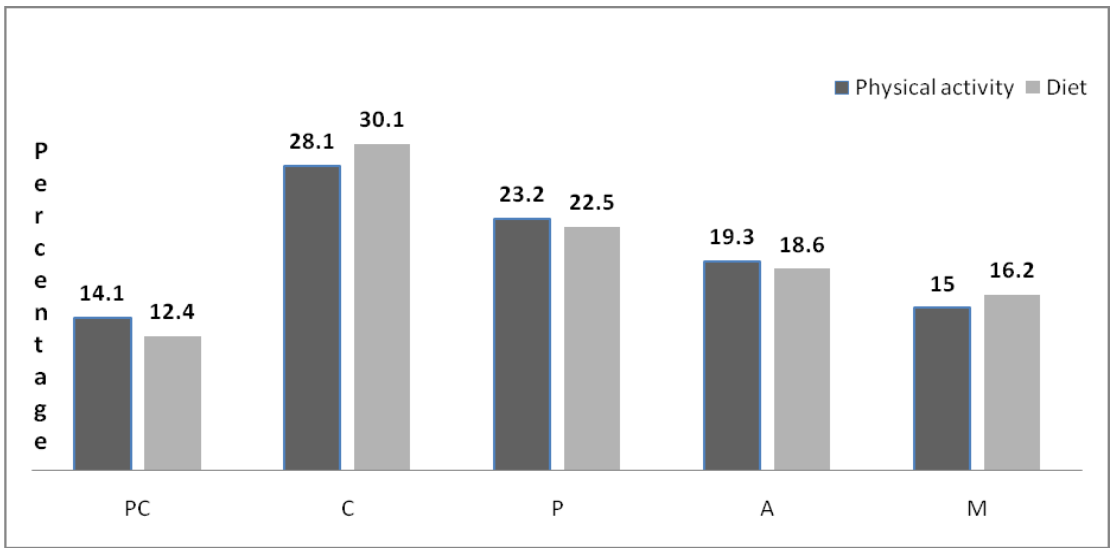
The baseline demographic, anthropometric, clinical, biochemical and lifestyle characteristics of the study group were analysed. The baseline and the changes in anthropometric, clinical, biochemical and lifestyle characteristics at the end of the study are given in table 3.1 and 3.2 (Ramachandran 2013). Both groups were similar in all the characteristics, the groups were well matched. The response rate was 96% (n=517) at the final follow up. The mean duration of the follow-up was 20.2 $\pm$ 7.0 months. Twenty patients (10 in each group) did not report for any follow-up. Three patients (two [<1%] in the control group and one [<1%] in the intervention group) were diagnosed with T2D by treating physicians outside the trial. The changes in anthropometric, clinical, biochemical and lifestyle characteristics at the end of 2nd year was analysed using repeated measures ANOVA. The results showed no significant difference in body mass index, waist circumference, blood pressure, total

cholesterol and triglycerides, whereas beneficial effects of the intervention were observed in HDL-cholesterol and dietary energy intake. There was no change in physical activity level.

4.10.3.1 Baseline distribution of diet and physical activity in the 5 TTM stages

Figure 4.1 shows the distribution of dietary habits and physical activity profile in five stages of the transtheoretical model. At baseline 12 to 14% of the subjects were in the precontemplation stage. The greatest proportion of subjects was seen in the contemplation stage in both physical activity and diet practices. A gradual decline occurred from preparation to maintenance stage (23.2% to 15%) in the number of subjects following healthy diet habits and physical activity practices. The percentage of participants in the action and maintenance stages were lower in both groups.

Figure 4.1: Baseline distribution of the study subjects with regard to dietary habits and physical activity practice profile in the 5 stages of the transtheoretical model

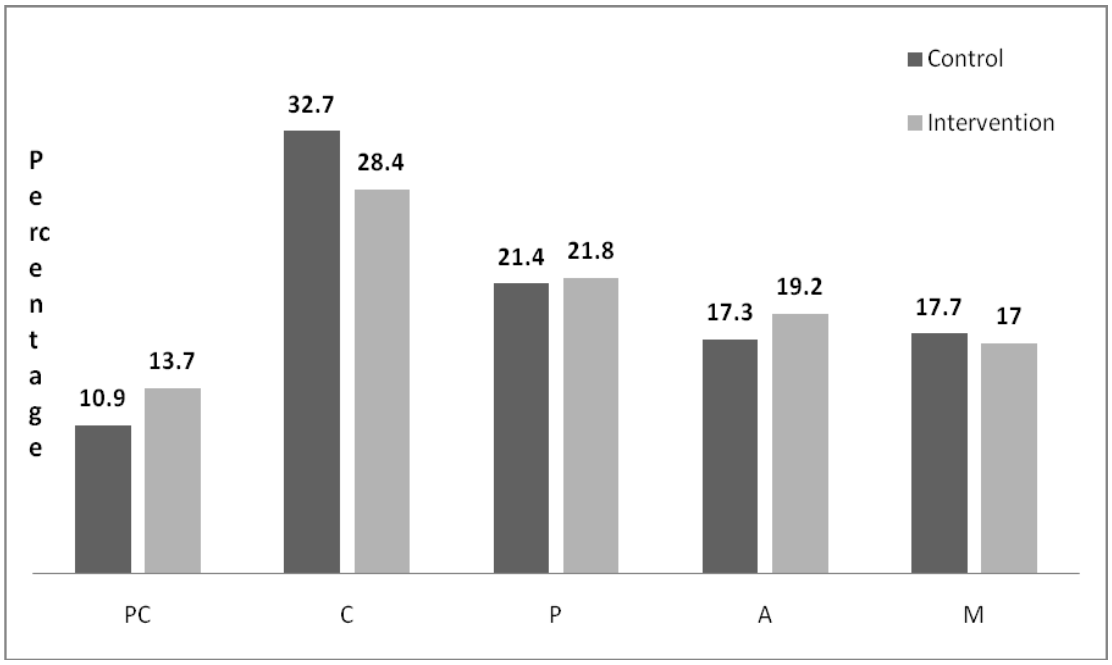


PC – Precontemplation, C – Contemplation, P – Preparation, A – Action, M - Maintenance

4.10.4 Diet analyses

Figure 4.2 shows the distribution of dietary practices based on transtheoretical model in the control and intervention groups at baseline. The figure shows that, at entry, a smaller percentage of subjects' were in the precontemplation stage in both groups, and the maximum percentage (32.7%) of participants in both groups were in the contemplation stage. Approximately 17% of the subjects were in the action and maintenance stage and were following healthy diet practices for six months or more.

Figure 4.2: Distribution of dietary practices of the study subjects with regard to the 5 TTM stages



PC – Precontemplation, C – Contemplation, P – Preparation, A – Action, M - Maintenance

Table 4.1 shows the shift in each of the TTM stages (precontemplation, contemplation, preparation, action and maintenance stages) from baseline to the end of the study. For the purpose of analysis the subjects were grouped into two main stages (pre-action and action stages). Precontemplation, contemplation and preparation stages were grouped as pre-action stage, and the action and maintenance stages as action stage. The rationale behind these two major categories is that the subjects in the first three stages are those who are not following healthy diet practices regularly and are in the process of changing to healthy diet practices. By contrast, the subjects' in the last two stages (action and maintenance) are those who have already started and are maintaining healthy diet practices for the last six months or more, and are therefore grouped into the action stage.

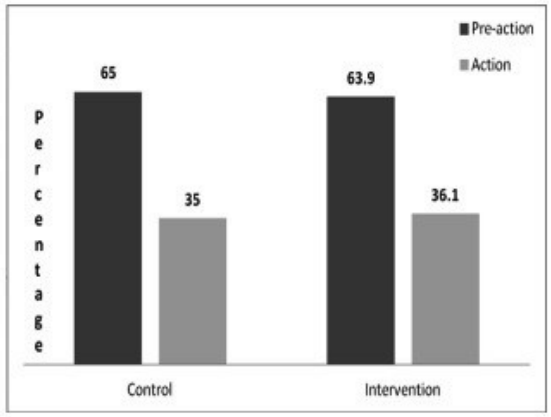
The distributions of study subjects in the pre-action and action stages in dietary practices are shown in figure 4.3. The data showed that at baseline the percentages in both control and intervention groups were similar in the pre-action and action stage, the groups were well matched. Significant differences were observed between the two groups in the pre-action and action stages at six and 24 months follow up ($p < 0.05$). No difference was observed at 12 and 18 months of follow up. Higher numbers of participants were in the action stage at 6 and 24 months ($p < 0.05$).

Table 4.1: Distribution of study subjects in the control and intervention groups with regard to diet practices at baseline and follow up

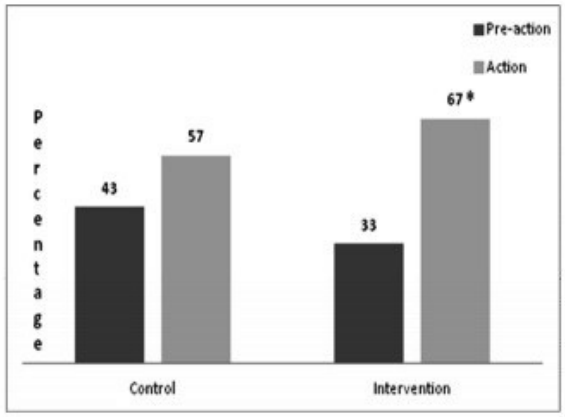
TTM Stages	Baseline		6 Months		12 Months		18 Months		24 Months	
	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention
Precont	29 (10.9)	37 (13.7)	-	-	-	-	-	-	-	-
Cont	87 (32.7)	77 (28.4)	13 (5.7)	18 (7.3)	15 (6.2)	8 (3.2)	12 (5.3)	16 (6.9)	11 (5.0)	14 (6.0)
Prep	57 (21.4)	59 (21.8)	85 (37.3)	63 (25.7)	67 (27.8)	60 (24.0)	63 (28.0)	50 (21.6)	64 (28.8)	53 (22.7)
Action	46 (17.3)	52 (19.2)	77 (33.8)	107 (43.7)*	102 (42.3)	112 (44.8)	99 (44.0)	108 (46.8)	101 (45.5)	99 (42.5)*
Maint	47 (17.7)	46 (17.0)	53 (23.2)	57 (23.3)*	57 (23.7)	70 (28.0)	51 (22.7)	57 (24.7)	46 (20.7)	67 (28.8)*

N and percentages are shown, inter group difference *p value < 0.05

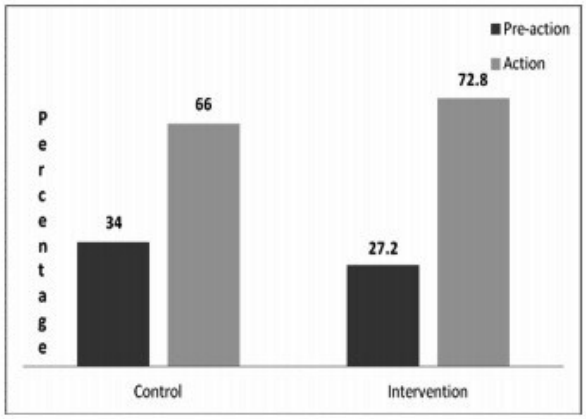
Figure 4.3: Distribution of study subjects in the pre-action and action stages in the control and intervention groups with regard to diet practices at baseline and follow up



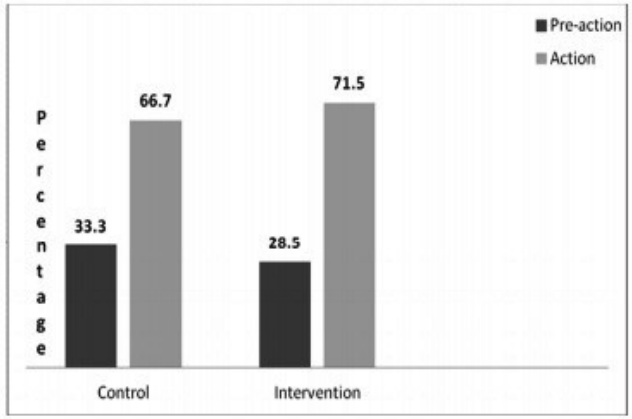
Baseline



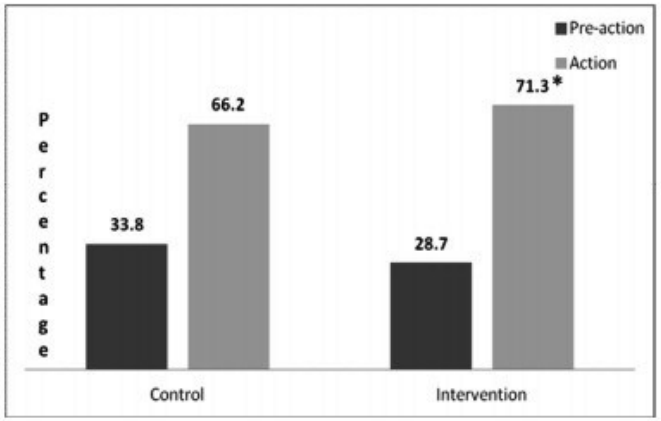
6 Months



12 Months



18 Months



24 Months

Percentages are shown, inter group difference *P value < 0.05

The distribution in consumption of carbohydrate, protein, fat, fibre and total kilo calories among the two groups was compared from baseline to follow up (table 4.2). Results showed that the groups differed significantly in carbohydrate consumption ($p < 0.002$) and total calorie consumption ($p < 0.005$) at 24 months follow up. On analysis of within group data, a significant difference was observed in carbohydrate consumption in both groups. The intervention group showed significant reduction in protein consumption, the control group improved in protein consumption. Although fat consumption improved in both groups, the improvement was greater in the intervention group than the control group. The control group showed greater improvement in fibre consumption than the intervention group. Both the groups significantly reduced total calorie consumption from baseline to follow up.

Table 4.2: Dietary components – Comparison of baseline and follow up data at 2 years

Diet parameters	Group	Baseline	6 month	12 month	18 month	24 month	P value Within group
CHO (gms)	Control	323.20 ± 45.96	308.42 ± 46.95	302.20 ± 48.48	301.19 ± 43.32	300.16 ± 41.00	<0.0001
	Intervention	322.91 ± 51.44	300.62 ± 49.17	298.94 ± 50.13	292.86 ± 47.30	287.02 ± 43.68**	<0.0001
Protein (gms)	Control	69.88 ± 12.24	68.11 ± 11.99	67.55 ± 11.29	68.40 ± 11.90	67.96 ± 11.72	NS
	Intervention	71.04 ± 13.61	68.14 ± 13.76	68.18 ± 13.43	67.70 ± 13.64	66.25 ± 12.93	0.003
Fat (gms)	Control	58.54 ± 12.47	56.70 ± 11.65	55.71 ± 10.92	55.46 ± 10.76	55.59 ± 11.32	0.01
	Intervention	60.97 ± 14.31	57.49 ± 12.32	57.36 ± 11.94	55.93 ± 11.70	54.54 ± 11.62	<0.0001
Fibre (gms)	Control	30.00 ± 7.64	30.52 ± 7.56	31.14 ± 7.54	31.53 ± 7.61	31.83 ± 7.63	<0.0001
	Intervention	30.48 ± 8.61	30.95 ± 8.08	31.09 ± 7.55	30.91 ± 7.81	31.25 ± 7.71	NS
Total calories (Kcals)	Control	2100.50 ± 278.33	2010.21 ± 267.06	1983.33 ± 259.69	1973.56 ± 254.95	1972.28 ± 248.40	<0.0001
	Intervention	2121.16 ± 295.67	1984.39 ± 281.11	1979.02 ± 284.38	1944.89 ± 278.10	1899.85 ± 255.54*	<0.0001

Mean ± S.D. are shown. Between group difference using independent 't' test *P < 0.005, **p < 0.002, within group difference was analysed using one way ANOVA.

Differences in consumption of carbohydrate, protein, fat, fibre and total calories were analysed between subjects who were adherent and non-adherent to the diet principles (diet recommendations and adherence categorisation was shown in table 2.2). Subjects' who were adherent were better in following healthy diet principles than non-adherent subjects (table 4.3). A significant difference was observed in carbohydrate, protein, fat, fibre and total calorie consumption among the two groups ($p < 0.0001$).

Table 4.3: Differences in carbohydrate, protein, fat, fibre and total calorie consumption among the adherent and non-adherent study subjects at baseline

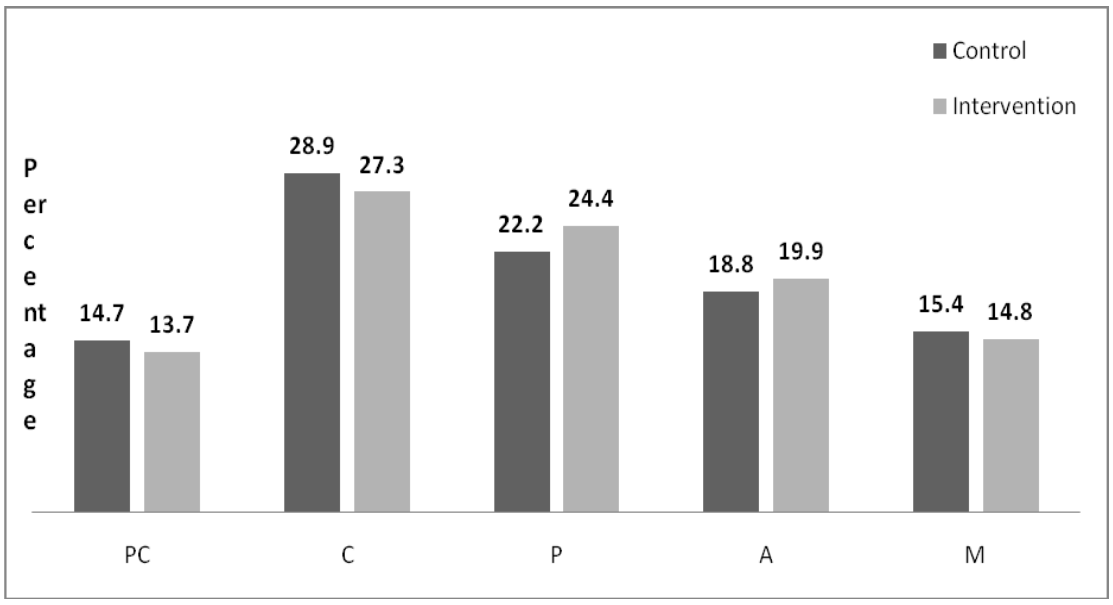
	Non-adherent (N=261)	Adherent (N=276)	P value
Carbohydrates (gms)	350.33 ± 44.48	297.25 ± 37.27	<0.0001
Protein (gms)	77.17 ± 11.91	64.13 ± 10.48	<0.0001
Fat (gms)	64.72 ± 13.69	55.08 ± 11.47	<0.0001
Fibre (gms)	31.62 ± 7.23	28.93 ± 8.7	<0.0001
Total Calories (Kcals)	2295.79 ± 250.32	1936.11 ± 195.81	<0.0001

Mean ± S.D. is shown, Independent sample 't' test is used to analyse the difference.

4.10.5 Physical activity analysis

Figure 4.4. Shows the distribution of physical activity practices among control and intervention group subjects' based on the transtheoretical model stages at baseline. The distribution was similar to that of the diet practices. A small percentage of participants were in the precontemplation stage and the highest proportion was in the contemplation stage. Smaller percentages were in action and maintenance stages. The inter group differences were not statistically significant.

Figure 4.4: Distribution of physical activity practices of the study subjects with regard to the 5 TTM stages



PC – Precontemplation, C – Contemplation, P – Preparation, A – Action, M – Maintenance

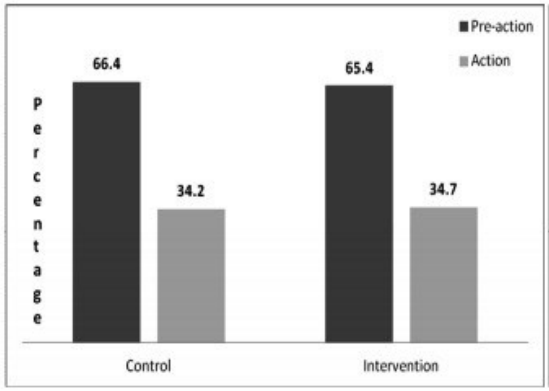
Table 4.4 shows the distribution in TTM stages from baseline to the end of the study in physical activity practices of the study groups. The distribution of study subjects in five TTM stages was categorized into pre-action and action stages as for their diet practices. The distribution of the study groups in these categories is shown in figure 4.5. The results showed that there was no difference at baseline between the study groups in the pre-action and action stages. Significant change was observed between the two groups in the pre-action and action stages only at six months follow up ($p < 0.05$). No difference was observed in 12, 18 and 24 months follow up.

Table 4.4: Distribution of study subjects in the control and Intervention groups with regard to physical activity practices at baseline and follow up (N and percentages are shown)

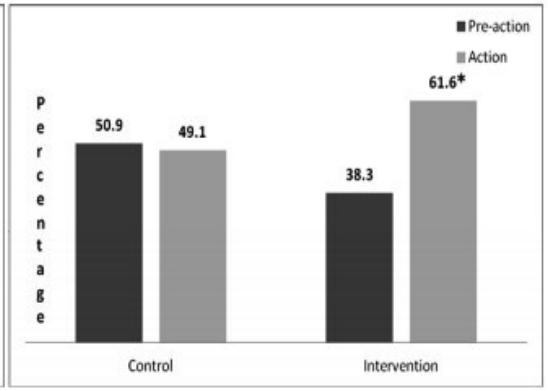
TTM Stages	Baseline		6 Months		12 Months		18 Months		24 Months	
	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention	Control	Intervention
Precont	39 (14.7)	37 (13.7)	-	-	-	-	-	-	-	-
Cont	77 (28.9)	74 (27.3)	21 (9.2)	17 (6.9)	12 (5.0)	9 (3.6)	10 (4.4)	5 (2.2)	29 (13.1)	17 (7.3)
Prep	59 (22.2)	66 (24.4)	95 (41.7)	77 (31.4)	106 (44.0)	96 (38.4)	94 (41.8)	75 (32.5)	91 (41.0)	86 (36.9)
Action	50 (18.8)	54 (19.9)	66 (28.9)	94 (38.4)*	90 (37.3)	96 (38.4))	80 (35.6)	88 (38.1)	80 (36.0)	87 (37.3)
Maint	41 (15.4)	40 (14.8)	46 (20.2)	57 (23.3)*	38 (13.7)	44 (19.6)	49 (18.2)	55 (27.3)	30 (9.9)	35 (18.5)

N and percentages are shown, inter group difference*p value < 0.05

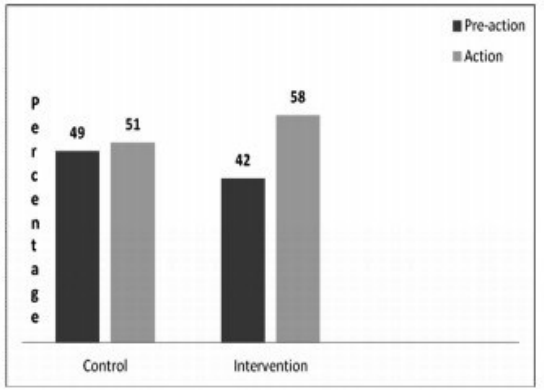
Figure 4.5: Distribution of study subjects in the pre-action and action stages in the control and intervention groups with regard to physical activity practices at baseline and follow up



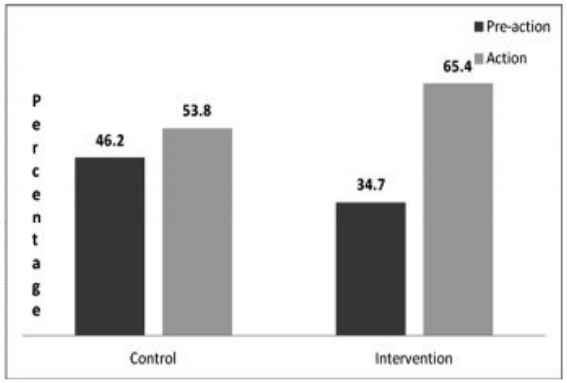
Baseline



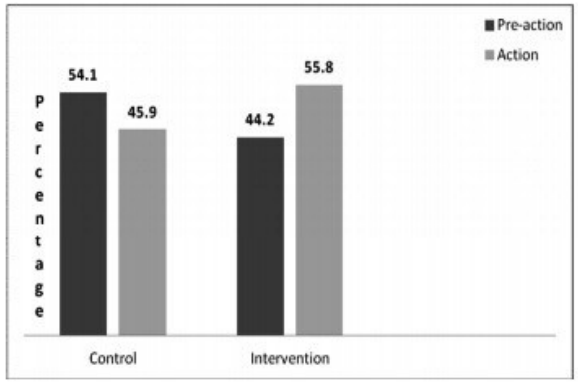
6 Months



12 Months



18 Months



24 Months

Percentages are shown, inter group difference *P value < 0.05

4.10.6 Change in TTM stage and its effect on glycaemic status

At the end of the follow up the participants were grouped as normal glucose tolerance (NGT), IGT and diabetes mellitus (DM), based on their glycaemic status at the end of follow up. Chi-square test was used to analyse the shift in TTM stages. Table 4.5 shows the distribution of subjects in 5 TTM stages in relation to their glycaemic status at baseline and follow up. At the end of follow up, a significant shift was observed in the action stage in all three diagnostic categories ($p<0.0001$)

The TTM stages were subdivided as pre-action (precontemplation, contemplation and preparation) and action stage (action and maintenance). In all the three sub-groups the percentage in pre-action stage had decreased significantly (Table 4.6). Correspondingly the percentages in action stage had increased significantly. The percentages of subjects shifted to the action stage shown in table 4.6. Although there was an improvement in the sub-groups, the percentage shifted (62.8%) in the IGT to DM group was significantly lower compared to the other two categories (70.5% and 73.7%).

Table 4.5. Change in TTM stages in relation to the final glycemic outcome. (n and %) are shown

TTM stages	Glycaemic outcome					
	IGT – NGT		IGT – IGT		IGT – DM	
	Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
Precontemplation	25 (14.7)	Nil	26 (11.6)	Nil	15 (12.2)	Nil
Contemplation	55 (32.4)	8 (4.7)$^{\$}$	64 (28.6)	4 (1.8)*	34 (27.6)	4 (3.3)
Preparation	36 (21.2)	42 (24.7)	49 (21.9)	55 (24.6)	32 (26.0)	42 (34.1)
Action	26 (15.3)	81 (47.6)$^{\#}$	51 (22.8)	95 (42.4)$^{\#}$	21 (17.1)	52 (42.3)$^{\#}$
Maintenance	28 (16.5)	39 (22.9)	34 (15.2)	70 (31.3)$^{\#}$	21 (17.1)	25 (20.3)

χ^2 test is used, $^{\#}p<0.0001$, $^{\$}$ p=0.008, *p=0.011

Table 4.6. Participants shift in TTM stages from pre-action to action stage in relation to the final glycemic outcome. (n and percentage are shown)

TTM stages	Glycaemic outcome					
	IGT – NGT		IGT IGT		IGT – DM	
	Baseline	Follow up	Baseline	Follow up	Baseline	Follow up
Pre-action	116 (68.3)	50 (29.4)	139 (62.1)	59 (26.4)	81 (65.8)	46 (37.4)
Action	54 (31.8)	120 (70.5)*	85 (38.0)	165 (73.7)*	42 (34.2)	77 (62.8)*

*p<0.0001

Table 4.7. Shift from pre-action to action stage in the different glycaemic group

Glycaemic status	Percentage of subjects shifted to action stage	χ^2	P Value
IGT – NGT	38.8	49.733	<0.0001
IGT – IGT	35.8	56.484	<0.0001
IGT – DM	28.5	18.817	<0.0001

4.10.7 Lifestyle goals achieved

The changes in dietary habits and regular physical activity at the end of the study are shown in table 4.8. The subjects in the intervention group were more likely to report changes in dietary habits compared with the control group. There was no difference in levels of physical activity or change in BMI between the study groups. Table 4.8 shows that among the beneficial goals achieved, the greatest was for reduced BMI (OR: 0.15 [95%CI: 0.01-0.47]), followed by reduction in portion size (OR: 0.39 [95% CI: 0.25-0.60]), reduction in oil intake (OR: 0.46 [95% CI: 0.30-0.69]) and reduced consumption of carbohydrates (OR: 0.52 [95% CI: 0.34-0.78]). Improvement in the physical activity was not observed at the follow-up.

Table 4.8: Change in dietary and exercise habits in the study groups at the end of the study period

Variables n (%)	Control (n=256)	Intervention (n=261)	Pvalue ᵀ	OR (95 % CI) (all subjects)
Decreased consumption of carbohydrates *	121 (47.3)	149 (57.1)	0.025	0.52 (0.34-0.78)
Decreased portion size*	107 (41.8)	137 (52.3)	0.015	0.39 (0.25-0.60)
Decreased consumption of oil intake *	124 (48.4)	162 (62.1)	0.002	0.46 (0.30-0.69)
Decreased BMI of at least 1 unit (Kg/m^2)	34 (13.3)	27 (10.3)	0.301	0.15 (0.01-0.47)
Regular physical activity §	197 (76.9)	202 (77.4)	0.899	1.14 (0.70-1.89)

***: Nutrient intakes were calculated from diet questionnaire**

ᵀ: P values were determined by the chi-square test between the two groups

§ : Exercise habits were assessed by self-reported physical activity questionnaire.

OR: odds ratio; CI: confidence intervals.

4.10.8 Incidence of T2D in relation to lifestyle goal achieved

The diabetes incidence in the study groups was analysed in relation to the number of lifestyle goals achieved by the participants. The total success score that could be achieved was 5. As shown in table 4.9, there was a strong inverse correlation between the success score and the incidence of diabetes. A larger percentage of participants in the intervention group achieved higher score than those in the control group. Among the 15 subjects who did not achieve any of the lifestyle goals (control: 12; intervention: 3), 8 (53%) developed diabetes. None of the subjects who achieved all the five lifestyle goals (control: 5; intervention group: 13) developed diabetes. The proportion of subjects with ≥ 3 lifestyle goals was higher in the intervention than in the control group (132 (50.6%) vs. 105 (41%); P=0.028). Multivariable logistic regression analysis, adjusted for baseline values of age, BMI and 2 hour glucose, showed that subjects who achieved ≥ 3 goals were at reduced risk of developing diabetes (odds ratio: 0.30 [95% CI: 0.19-0.48]; P<0.0001) compared with the subjects who achieved <3 goals.

Beta cell function improved by 11.4% in those who achieved ≥3 goals [(baseline: 150.3 (IQR: 119.4-181.2); follow-up: 167.4 (IQR: 118.8-217.6); P<0.0001)] whereas it deteriorated by 12.6% in subjects who achieved <3 goals [(baseline: 153.1 (121.7-186.4); follow-up: 134.2 (IQR: 95.0-192.9); P<0.0001)]. Concurrently, improvement in compliance levels resulted in approximately 21% improvement in insulin sensitivity (baseline: 2.4±1.2; follow-up: 2.9±1.7; P<0.0001), whereas there was no significant improvement observed in those who achieved <3 goals (baseline: 2.3±1.4; follow-up: 2.2±1.6; P=0.275).

Table 4.9: Diabetes incidence rate by lifestyle goals (number of intervention goals achieved at year 2)

Success score (n)	Control	Intervention	Incidence of DM in Control n (%)	Incidence of DM in Intervention n (%)
Zero (15)	12	3	6 (8.2)	2 (4.0)
One (101)	59	42	23 (31.5)	16 (32.0)
Two (164)	80	84	22 (30.1)	20 (40.0)
Three (135)	61	74	15 (20.5)	8 (16.0)
Four (84)	39	45	7 (9.6)	4 (8.0)
Five (18)	5	13	Nil	Nil

N and percentage are shown

4.11 Discussion

4.11.1 Diet

Our study in a high risk population for developing diabetes applied the TTM to tailor text messages sent through SMS to motivate and educate high risk individuals to prevent diabetes. This approach was found to be effective in producing LSM-related to dietary changes which improved the final outcome i.e., reduction in incidence of diabetes in the intervention group versus control group receiving standard care. The TTM stages of change has been one of the most widely used behavioral theories applied in studies addressing unhealthy lifestyles, including smoking cessation and substance abuse. A recent meta-analysis (Noar 2007) showed positive results, although a few studies have not supported use of the TTM (Pratapsingh 2011). Neverthless, the TTM stages of change interventions targeting changes in diet or physical activity or both most frequently resulted in significant improvement in dietary consumption (change in calorie intake or change in daily fruit and vegetable intake. (Johnson 2008; Jones 2003; Logue 2005)

In our study, at baseline, a small proportion of subjects were in the precontemplation stage with regard to both diet and physical activity practices, indicating that some participants were unaware of the benefits of healthy lifestyle practices. The majority of the subjects were in the contemplation stage and they were aware of the benefits of healthy lifestyle and intended to change in the next six months. Nearly 23% of the subjects were in the preparation stage, and were in the process of changing, working out strategies to change their behavior, and nearly 19% of the subjects were in the action and maintenance stages and had changed their lifestyle in the last six months or more. Overall larger numbers of subjects were in the pre-action stage and only very small numbers were in the action phase and were

following healthy lifestyle. The distribution of subjects in all the five TTM stages was similar in both groups at baseline.

At baseline the distribution of participants in the TTM stages was similar in the two groups with respect to diet practices. At the six months follow up a greater proportion of participants in the intervention group had shifted to the next TTM stage. Similar stages of change have been reported in dietary behaviour (Johnson 2008; Jones 2003). The trend continued till the end of the study. It is well known that within the TTM stages, relapses are almost inevitable and become a part of the process of working toward life-long change (Zimmerman 2000). But although subjects moved forward and backward in their TTM stages, no subject relapsed to the precontemplation stage. This could have been due to awareness creation, personalized education on diabetes and other chronic diseases, and on the benefits of healthy lifestyle through SMS. This observation was unique in comparison with the results of behavioural studies concerning smoking cessation and substance abuse, which had used TTM theory for tailoring the intervention. In these, subjects remained in or relapsed to the precontemplation stage. The difference might have been due to the fact that, these studies concerned addictive behavior (pleasure principle i.e., change at the behavioral level) in which participants did not want to change. In our study unhealthy diet practices and sedentary lifestyle were not addictive behaviors, and could be modified with better education and motivation. They could be modified due to creation of better awareness/ education.

In the diet practices, inter group differences were not seen at baseline and at 12 and 18 months during the study, but significant differences were observed at 6 months and at the end of the study. A larger number of participants in the intervention group shifted to action stage compared to the control group. This trend was similar to that of a study conducted for weight reduction through diet practices

using mobile phone SMS (Kim 2007) and another study (Yoo 2009) which used an internet email messaging service for weight reduction using healthy diet practices. The previous studies showed that any information technology-based (internet email service or SMS) interventions would have an immediate effect on behavior, but these strategies were not shown to have a sustained effect on dietary changes. Most of the studies using information technology were short term studies (less than six months) (Krishna 2008), hence the results could not be compared with the present study. In our study healthy dietary practices were sustained for 24 months, although the changes were seen only after a year. Continuous motivation and education via TTM-staged message delivery helped to produce sustained behavioural change resulting in significant reduction in the incidence of diabetes.

Diet consumption was measured using a validated food frequency questionnaire. (Ramachandran 2006) Significant reduction in carbohydrate consumption was seen in both groups and the change was more marked in the intervention group than in the control group. The intervention group had good adherence to the dietary advice and exhibited changes in consumption of carbohydrate, fat and total calories. The difference was statistically significant in the adherent group Vs the non-adherent group ($p < 0.0001$). Protein and fibre consumption was better in the non-adherent subjects. However, there was no significant improvement in BMI and physical activity levels in the two groups.

There was a strong association between the number of lifestyle goals achieved and reduction in the incidence of diabetes. The intervention group which received TTM based SMS messages achieved more goals and there was a lower incidence of diabetes, which was statistically significant when compared with control group (hazard ratio 0·64, 95% CI 0·45–0·92; p=0·015). Therefore constant motivation using educational messages which are appropriate for the TTM stages

had helped in achieving the desired effect. Subjects who achieved all 5 goals did not develop diabetes in the study period.

4.11.2 Physical activity

The baseline physical activity practices were similar in both control and intervention groups. Significant differences were observed between the groups in physical activity practices in the first six months follow up, with physical activity level significantly improving in the intervention group compared with control. However, the trend did not continue untill the end of the study in spite of constant motivating reminders by SMS to improve physical activity. Nevertheless, there have been studies (Johnson 2008; Logue 2005; Mastellos 2014) which reported that improvement in physical activity could be observed using TTM stages of change in their study population.

Our study cohort comprised industrial workers, and the majority were skilled workers involved in strenuous jobs, hence they could not continue to do additional physical activity despite the motivation received through the intervention strategy. Most of the study participants were working in shift system (shift change once in 3 days or once in a week). The shift system might disturb or intervene in adapting to the regular physical activity practices. This would not be the case in diet practices where the participant had control over his diet pattern.

In several diabetes prevention studies (DPP, DPS and IDPP1) improvement in physical activity was seen in intervention group. The prevention trials had used different strategies to change the lifestyle of prediabetic participants. The DPP and DPS studies had used a comprehensive and structured educational programme addressing self-management strategies such as: barriers to adherence, evaluating

goals, addressing triggers for behavioral relapse, and educating participants about the benefits of LSM (Diabetes Prevention Program Research Group 2002; Uutela 2004). In the DPP study improvement in physical activity was achieved by providing lifestyle coaches with a 'tool-box' of adherence strategies (Diabetes Prevention Program Research Group 2002). The Indian Diabetes Prevention Programme 1 (Ramachandran 2006) showed an improvement in physical activity in the LSM group from 41.7% to an average of 58.8% through individual counselling at baseline and at 6-monthly intervals, as well as with monthly contact via telephone.

All the above studies demonstrated improvement in physical activity, but mainly through personal contacts, face-to-face counselling, personal feedback and motivation with the participants. Possibly, more studies of TTM and SMS in a less physically active intervention group are needed to produce sustained improvement in physical activity.

A significant percentage of participants moved to the action and maintenance stages. The percentages were significantly more in the groups which became NGT or remained IGT when compared to those who developed diabetes. Accordingly development of diabetes could be attributed to smaller percentage of participants being in the action stage. Moreover it is possible that the tenure of the action stage might have been shorter in those who developed diabetes.

Although, both the groups received LSM advice at baseline, the adherence and success scores were higher in the intervention group ($p=0.028$). The better adherence to LSM, specifically to dietary principles observed in the intervention group can be ascribed to the impact of TTM stage-based messages received by them. The utility of tailored SMS messages in motivating the participants to follow the intervention strategy was endorsed by the findings.

4.11.3 Interpretation

This study has shown that participation in a lifestyle intervention trial to prevent diabetes sensitised participants to change their lifestyle both in the control and in intervention groups. But, the change was significant only in the intervention group, in which participants received constant motivating reminders about healthy lifestyle. Significant improvement was observed only in diet practices and not in physical activity. SMS was effective in changing the unhealthy diet practices. However, many had strenuous work- related physical activity which may have limited the ability of the study to distinguish effects of change in physical activity.

A few previous studies had shown that weight loss could be achieved through changes in dietary practices and improvement in physical activity. In this study, there was no significant weight reduction, but significant change was seen in dietary habits. Change in dietary habits likely contributed to a reduction in incidence of T2D, which was achieved independent of weight change. The analysis showed that there was a significant improvement in the beta cell function as indicated by an improvement in the disposition index.

4.12 Conclusion

The study demonstrated the following:

- TTM based motivating / educating SMS was an effective tool in preventing T2D mellitus among Asian Indian men with IGT.
- The messages were effective in improving dietary practices leading to significant improvement in the glycaemic outcome in an intervention period of 2 years.

- Significant motivational impact was not produced by the strategy on the physical activity levels.

  This might have been due to the fact that majority of the participants already had good level of occupational activity and therefore changes could only be made in their dietary practices. Alternatively sustained changes in physical activity habits were more difficult to practice regularly and needed more intensive motivation tool than SMS.

- More studies are needed to confirm the above observations.

AWARENESS ON GENERAL HEALTH AND DIABETES

5.1 Introduction

Diabetes is one of the most common non-communicable diseases (NCDs) present in all parts of the world. It is the fourth or fifth leading cause of death in developed countries and also in developing countries. There is a global increase in the prevalence of diabetes and its major impact is observed in the Western Pacific countries (138.2 million adults) followed by South East Asian countries (72.1 million people with diabetes); half of the people with diabetes may be undiagnosed (IDF Diabetes Atlas 6th ed. 2013). Undoubtedly, diabetes is one of the most challenging health problems of this century.

India is positioned 2nd (65.1 million adults) among the top ten countries for the largest number of people with diabetes (IDF Diabetes Atlas 6thed 2013). India has varied social, cultural, economic and education patterns. Several regions in this country are still under-developed and the people have many beliefs, practices and misunderstandings about diabetes (Shobhana 1999). The traditional lifestyle of South Asians, characterized by a diet consisting of complex carbohydrates, low saturated fat and a good amount of physical activity, has been protective against cardiovascular disease and diabetes, even in the presence of a strong genetic predisposition. Overweight and obesity are increasing rapidly in Asia with the global shift in diet towards energy-dense foods and sedentary lifestyle. These changes, originally observed in Asian immigrants in affluent countries, are now manifested even within the native lands (Ramachandran 2010; Chan 2009; Lee 2011; Hu 2011). Rapid urbanization and industrialization has resulted in drastic changes in lifestyle all over the world but its impact is more felt in developing countries like India because of its rapid transition. One of the effects of this transition is a change in disease

patterns with communicable diseases being replaced by NCD's or lifestyle diseases, including diabetes, obesity, hypertension, stroke, cardiovascular disease and cancer (Omran 1971). This growing epidemic is now considered as a major public health problem in developing countries such as India as it drains between 5 – 25% of the family income of an average Indian (Shobhana 2000) which amounts to 2.2 billion US dollars per annum (Bjork 2003; Raheja 2001). The quality of life is also affected in the young adults who are affected by the disease in their most productive age.

There is very sparse data on the level of awareness about diabetes among the general public and diabetic subjects in India. Such information is important for the formulation of public health policies with specific reference to implementation of national diabetes control programmes. Knowledge about the level of awareness on causes, effects and complications of diabetes in a population is important in formulating a prevention programme for diabetes.

Chennai is a metropolitan city with a substantial proportion of diabetic people (18.6%) (Ramachandran 2008). The city also has an adequate number of diabetes specialty hospitals, corporate hospitals and diabetic special wards in government hospitals to cater to the needs of the large diabetic population. People of Chennai have repeated media exposures, with press, television and radio providing key messages on diabetes management and on prevention of diabetes complications. They are also exposed to several diabetes screening camps and campaigns and diabetes awareness programmes in educational institutions and software as well as in other organizations and banks. Despite these adequate diabetes care facilities, studies have shown that the awareness level is generally poor in the general public and among diabetic people (Murugesan 2007; Deepa 2005; Sukanta 2012). The findings emphasize the immediate need for strategies to impart knowledge about

diabetes in the society and also to the medical practitioners, para-medical personnel and other medical staff.

The recommendations made by these awareness studies have paved the way for the formulation of the National Programme for Prevention and Control of Diabetes, Cardiovascular Diseases and Stroke (NPDCS) by the government of India. The programme was initiated in the year 2010 to strengthen infrastructure, human resource development, health promotion, early diagnosis, treatment and referral. It was implemented in 100 backward and remote districts across 21 States during 2010-12. The focus of NPCDCS is on promotion of healthy life styles, early diagnosis and management of diabetes, hypertension, cardiovascular diseases & common cancers e.g. cervix cancer, breast cancer and oral cancer. Our centre, the India Diabetes Research Foundation (IDRF) and Dr. A. Ramachandran's Diabetes Hospitals served as one of the nodal centres in conducting training for doctors and paramedical personnel. We have trained more than 3000 doctors and more than 10000 paramedical personnel of public and private hospitals in this country.

Based on the outcome of the earlier studies conducted in Chennai and other parts of India on knowledge, awareness and practice concerning general health and diabetes, in the present diabetes prevention programme study, the level of awareness was assessed among study participants according to socioeconomic, demographic, cultural, occupation and educational background, in the context of an awareness creation strategy through SMS.

5.2 Methods and Materials

5.2.1 Aim

To improve the general health awareness and diabetes awareness level using SMS.

5.2.2 Objectives

To analyse the difference in:

- General health and diabetes awareness at baseline and at the end of follow up.
- General health and diabetes awareness level between subjects with no family history of diabetes and with family history of diabetes.
- General health and diabetes awareness level among subjects with history of hypertension and no history of hypertension.
- Awareness level according to different educational background of the study subjects.
- Awareness level according to different glycemic conditions of the study subjects, at the end of the study.

5.2.3 Research design

We undertook this prospective, parallel-group (control 266 and intervention 271), randomised controlled trial at two cities in South East India. Participants in the intervention group received frequent mobile phone messages compared with controls who received standard lifestyle modification advice at baseline only.

5.2.4 Participants

Working Indian men were screened for eligibility to be included in the study by a questionnaire. The men were employed in public-sector and private-sector industrial units in southeast India (Chennai, Tamil Nadu and Visakhapatnam, Andhra Pradesh). The study was done in the workplace and because 96% of the employees were men, we included only men in the trial. Participants' occupations were self-classed as unskilled, skilled, or clerical or executive.

5.2.5 Statistical procedure

To analyse the difference in baseline general health and diabetes awareness level between control and intervention groups, independent sample "t" test was used. To assess the effects of the intervention on awareness levels we used mixed-linear regression modelling with maximum likelihood parameter estimation for continuous variables. Differences in the estimated marginal means between the groups with 95% CIs are shown. one-way ANOVA was used to analyse the difference in awareness level according to the educational level of the study subjects and difference in awareness level according to different diagnostic condition of the study subjects.

5.2.6 Tool used

5.2.6.1 Awareness on general health and diabetes questionnaire

The questionnaire quantifying awareness level of general health and diabetes questionnaire was developed by Prof. A. Ramachandran (Murugesan 2007) and his team to assess the awareness level of the general health and diabetes of general public and diabetic subjects, standardised to the Indian population. The questionnaire comprises three sections: Section A is to collect information on the demographic characteristics of the participants. Section B (which is common to

general public and diabetic patients) which assesses the awareness on general health of the participants: the questions in this section comprise knowledge concerning physical activity, healthy and unhealthy diet and methods of improving health. Section C includes questions on diabetes which elicit information on knowledge regarding causes of diabetes, symptoms of diabetes, how diabetes affects daily life, complications and the possibility of preventing diabetes.

Each correct response is given a score of one The maximum score in each sub-domain are: physical activity (9), healthy and unhealthy diet (15), measures to improve health (9) and sources of information (1), causes of diabetes (7), symptoms of diabetes (7), affects daily life (4), complications (1), prevention (4). The maximum score for general health awareness and diabetes awareness level are 34 and 23 respectively. A copy of the questionnaire is included as appendix 3.

5.3 Results

The baseline general health and diabetes awareness level of the study subjects was analysed using independent sample “t” test. There were no significant difference between the control and the intervention group in awareness on general health and diabetes at baseline (table 5.1).

Table 5.1. Comparison of general health and diabetes awareness level among the control and intervention groups at baseline

Awareness	Awareness scores (Mean ± SD)		p value
	Control (266)	Intervention (271)	
Awareness on general health	23.99 ± 6.38	24.85 ± 6.42	0.120
Awareness on diabetes	14.57 ± 6.98	15.63 ± 6.85	0.076

Independent sample ‘t’ test was used, Mean and standard deviation are given.

In the analysis of the data at follow up we used mixed-linear regression analysis, taking visit and intervention into account to generate estimated marginal mean and difference and difference in mean change (95% C.I.) at the end of the follow up.

The data shows there was a significant difference in both general health and diabetes awareness level between the two study groups (table 5.2). Scores in the intervention group were significantly higher than that of the control group, from baseline to the end of the study.

Table 5.2. Difference in general and diabetes awareness level of the study subjects (control and intervention) at the end of the follow up

Variables	Baseline	12 months	24 months	Estimated marginal means	P value
General awareness					
Control	24.0±6.4	24.6±6.8	25.3±6.6	1.48(0.85-2.10)	<0.0001
Intervention	24.9±6.4	26.0±6.0	27.6±5.8		
Diabetes awareness					
Control	14.6±7.0	15.1±6.8	16.0±6.3	1.51(0.87-2.14)	<0.0001
Intervention	15.6±6.9	16.5±6.1	18.1±5.1		

Data are mean (SD). Mixed-linear regression analysis, taking into account visit and intervention, to generate estimated marginal means and difference in mean change (95% CI) at the end of follow-up

5.3.1 Impact of positive family history of diabetes mellitus

The baseline and follow up awareness level (general health awareness and diabetes awareness) was analysed (table 5.3) among groups of subject's with no family history of diabetes and with a positive family history of diabetes using independent sample 't' test. There was no significant difference in general health awareness between the groups at baseline or at 12 and 24 months follow up. Diabetes awareness level was also analysed between the two groups. An improvement in diabetes awareness level with positive family history was found, with significant differences demonstrated between the two groups at baseline (p=0.008) and 12 months follow up (p=0.014). However, there was no difference between the two groups in diabetes awareness at 24 months follow up.

Table 5.3. Differences in diabetes and general awareness level among the study subjects with and without family history of diabetes.

Follow up	Awareness scores (Mean ± SD)					
	General health awareness			Diabetes awareness		
	No family history	Positive family history	P value	No family history	Positive family history	P value
Baseline	23.95 ± 6.64	24.86 ± 6.18	0.100	14.27 ± 7.28	15.87 ± 6.52	0.008
12 Months	24.98 ± 6.53	25.55 ± 6.31	0.314	15.08 ± 6.53	16.48 ± 6.42	0.014
24 Months	26.14 ± 6.48	26.77 ± 6.16	0.259	16.79 ± 5.84	17.29 ± 5.69	0.324

Independent sample t test was used.

5.3.2 Impact of history of hypertension

Differences in general health awareness and diabetes awareness level were analysed with respect to participants' history of hypertension (table 5.4). Results showed that people with history of hypertension had higher general health awareness level (p=0.037) compared to participants with no hypertension. No difference was found in diabetes awareness level between people with and without hypertension

Table 5.4. Differences in diabetes and general awareness level among the study subjects in relation to history of hypertension

Awareness	Awareness scores (Mean ± SD)		P value
	No hypertension	History of hypertension	
Awareness on general health	24.07 ± 6.36	25.39 ± 6.51	0.037
Awareness on diabetes	15.01 ± 6.91	15.30 ± 7.12	0.678

Independent samples t test was used, Mean ± S.D. are given

5.3.3 Influence of education status

The impact of educational status on general health and diabetes awareness scores was studied (table 5.5). The data showed that, the subjects' awareness score varied significantly (p<.0001 for both general health and diabetes awareness) according to the educational qualification of the study subjects. Participants with professional qualification had the highest general health and diabetes awareness followed by college, technical and school education. Post-hoc analysis showed that participants with a professional qualification showed higher awareness level on general health compared to participants with school education (p<0.0001) and technical education (p<0.001). Similarly, participants with a professional qualification showed higher diabetes awareness level compared to participants with school education (p<0.0001), college education (p<0.030) and technical education (p<0.0001).

Table 5.5. Differences in awareness on general health and diabetes among the study subjects in regard to educational qualification at baseline

Awareness	Awareness scores (Mean ± SD)				P value
	Educational qualification				
	School	College	Technical	Professional	
Awareness on general health	22.75 ± 6.80	24.88 ± 6.18	23.88 ± 6.38	26.76 ± 5.68	<0.0001
Awareness on diabetes	12.89 ± 7.91	15.33 ± 6.89	14.57 ± 6.86	18.06 ± 5.10	<0.0001

*ANOVA was used to test for significant variation between the groups

5.3.4 Impact of diagnosis on awareness level

The study participants were categorised into three groups: normal glucose tolerance, IGT and diabetes, according to diagnosis at the end of the study. Awareness levels on general health and diabetes were analysed among the three groups (table 5.6). Significant variation was observed in general health awareness level (p=0.005) and in diabetes awareness level (p=0.020) between the three groups. The score of the subjects who became diabetic was less on both awareness levels when compared with the score of those who reverted to normal or who continued to have prediabetes. Post hoc analysis showed that, the awareness level on general health was low in participants who developed diabetes at the end of the study compared to participants who reverted to NGT (P<0.007) and IGT (P<0.013). In diabetes awareness level the IGT participants score significantly differed from the DM participants (p=0.018).

Table 5.6. Mean differences in diabetes and general health awareness among the three diagnostic groups at the end of the study.

Awareness	Awareness scores (Mean ± SD)			P value*
	NGT (170)	IGT (224)	DM (123)	
Awareness on diabetes	17.25 ± 5.77	17.59 ± 5.15	15.81 ± 6.60	0.020
Awareness on general health	27.12 ± 6.04	26.87 ± 6.26	24.86 ± 6.57	0.005

*ANOVA was used. NGT-Normal Glucose tolerance, IGT-Impaired Glucose Tolerance, DM-Diabetes mellitus.

5.4 Discussion

The major finding from this analysis was that frequent SMS was associated with an improvement in the study participants' awareness level on general health and diabetes at the end of two years. The awareness levels on diabetes in the general public and diabetic patients have been studied (Murugesan 2007; Deepa 2005; Sukanta 2012) but, none of the intervention studies assessed the impact of intervention on health awareness level of the study subjects. In the present study, SMS technology was used to improve the awareness level of the participants in the intervention group. The description of the delivery of SMS is given in detail in chapter 2 (Methodology). At baseline the general health awareness and diabetes awareness level was similar in both control and intervention groups. The SMS intervention was then associated with significant improvements in the awareness on general health and diabetes. The general health awareness level did not differ at baseline or follow up between participants with and without family history of diabetes but the diabetes awareness level was significantly higher among those with a positive family history of diabetes. This might be due to the presence of diabetes among the family members, which might have provided higher exposure to education regarding the disease either through the treating doctor or the media regarding the causes, effects, symptoms, management and complications of diabetes to take care of their own family members. This finding was supported by the survey conducted by Ramachandran et al., and awareness studies conducted in other parts of India (Murugesan 2007; Deepa 2005; Sukanta 2012; Prianka 2010) and one study in Pakistan (Naheed 2010) and other study in Nepal (Dinesh 2008) which showed that people with a family history of diabetes had a better awareness level than people without a family history. However, at the end of the study, the diabetes awareness level was similar in both groups. This may have been due to the health education

imparted at the baseline for both the groups. All participants in this diabetes prevention trial were educated on benefits of healthy lifestyle (healthy dietary habits and improved physical activity) and also their high risk of developing diabetes. Many participants gathered more information during the course of the study. In addition 50% of the participants received frequent SMS on healthy lifestyle which helped the participants with no history of diabetes to improve their knowledge.

The subjects with a history of hypertension had significantly higher general health awareness level than subjects with no history of hypertension. Level of diabetes awareness did not significantly differ between these two groups. Hypertension being a more common disease than diabetes, they would have gathered more knowledge on general health effects of hypertension and not specifically on diabetes. These findings also implied that people with hypertension are not aware of the fact that hypertension and diabetes are commonly associated, and that the risk factors and management strategies are similar for both the diseases. Therefore, more awareness education is needed on diabetes in people with hypertension.

Educational qualification had a significant impact on awareness levels. In participants with professional education, level of awareness on general health and diabetes was high followed by college, technical and school educational qualification. The mean awareness scores on general health and diabetes increased with level of education. This finding was corroborated by the reports of other two studies conducted in this country (Murugesan 2007; Deepa 2005). Persons with higher educational background would also have adopted healthy lifestyle practices (Ramachandran 2013).

The subjects' general health and diabetes awareness level differed according to their glyacemic status at the end of the study. The participants who reverted to normal glucose tolerance and those who continued to have IGT had a better awareness level than participants who developed diabetes at the end of the study. This suggests that the knowledge received through the baseline education and SMS about diabetes had resulted in adoption of better diet practices to reduce the incidence of T2D (Ramachandran 2013).

5.5 Summary of the findings

At baseline the awareness level on general health and diabetes was similar in both control and intervention groups. The scores improved significantly in the intervention group. Presence of family history of diabetes did not influence the score on general health and awareness either at baseline or at follow up but a significant of family history was observed in diabetes awareness level at baseline and 12 months follow up, albeit not in 24 months follow up. Presence of hypertension improved awareness on general health. The subjects with professional qualification had better awareness on both general health and diabetes followed by subjects with college education, and technical qualification. Level of education positively influenced the awareness levels.

5.6 Conclusion

Our study has shown that the SMS intervention helped to improve the general health and diabetes awareness level of the study participants at the end of the study. Therefore, an action plan has to be worked out to raise public awareness on diabetes and other lifestyle diseases such as hypertension and cardiovascular disease. Possibilities for raising awareness include outreach screening camps, and educational campaign programmes, and through mass media.

EFFECT OF TTM TAILORED SMS IN IMPROVING QUALITY OF LIFE IN INDIVIDUALS WITH PREDIABETES

6.1 Introduction

Diabetes is a chronic metabolic disease increasing worldwide and it has reached epidemic proportions in many developing countries. The escalating incidence of T2D is a major challenge to health care professionals and policy makers. It is widely accepted that having T2D is not only associated with increased morbidity and mortality, but also with a poor quality of life (Rubin 1999; Goldney 2004; Manuel 2004; Coffey 2002). Quality of life reflects a measure of physical and social functioning as well as mental health and is recognized as an important component of health (Commonwealth of Australia, National Diabetes Strategy 1999)

Maintaining or improving QOL is an integral part of the successful management of diabetes. Indeed, it is well-known that QOL improves with better glycaemic control (Jacobson 2004). Persistent uncontrolled glucose levels can lead to serious diseases affecting the blood vessels of all the vital organs; the eyes, heart, kidney and the nervous system. These complications will lead to poor QOL and reduced life expectancy. The diabetes control and complication trial (DCCT) has shown that, patients undergoing intensive diabetes treatment do not face deterioration in the quality of their lives, even while the rigor of their diabetes care is increased (DCCT Research Group 1996).

Recent studies have conclusively demonstrated that preventive approaches delay or prevent the onset of the disease. Prediabetes is recognized as being a stage preceding diabetes when blood glucose levels are higher than the normal level but below the threshold for diagnosis of the disease condition. The two prediabetic

conditions are IFG and/ or IGT (American Diabetes Association 2009) and IGT is the most common prediabetic condition prevalent in the world. People with IGT are at high risk of developing diabetes. Among adults aged 45 years and older, the prevalence of prediabetes is approximately 25% (Benjamin 2003; Dunstan 2002; Glumer 2003). Evidence suggests that moderate physical activity of at least 150 minutes per week, in combination with a 5 – 10% weight loss in overweight / obese persons, is associated with reduced risk of developing type T2D (DCCT Research Group 2002; Hamman 2006; Pan 1997; Tuomilehto 2001). The American Diabetes Association recommends the same for the prevention of T2D (Sigal 2004). This guideline also agrees with the current U.S. public health guidelines of achieving a minimum of moderate intensity physical activity for 30 minutes on at least five days a week or a minimum of 20 minutes of vigorous intensity physical activity on at least three days a week (Haskel 2007). Despite these guidelines and the wealth of evidence indicating favourable effects of physical activity on both physical and psychosocial health variables in populations other than those with prediabetes, little is known about the physical activity behaviors of individuals with prediabetes and about the stage in the development of diabetes at which quality of life begins to diminish. It is unknown whether quality of life is reduced at or prior to the onset of diabetes, among those with IFG and IGT.

There are studies which have shown that doctors' instruction or structured education programme helps to improve the QOL of the diabetic patients. (David McIntyre 2010; Baz 2011) In this study we aimed to test the outcome of TTM tailored SMS in improving the QOL of the participants with prediabetes.

6.2 Quality of life

Quality of life is defined as individuals' perceptions of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. (WHOQOL GROUP 1998) This definition reflects the view that QOL refers to a subjective evaluation which is embedded in a cultural, social and environmental context. Because this definition of QOL focuses upon respondents' "perceived" QOL, it is not expected to provide a means of measuring in any detailed fashion symptoms, diseases or conditions, but rather the effects of disease and health interventions on QOL. As such, QOL cannot be equated simply with the terms "health status", "life satisfaction", "mental state" or "well-being", so it is multidimensional, which is reflected in the WHOQOL-100 structure (The WHOQOL Group 1994a; 1994b). The definition focuses on the impact of disease and effect of interventions on the QOL, rather than on the diseases and their associated symptoms. Standard indicators of the QOL include not only wealth or social status and employment, but also the built environment in which we live, physical health, mental health, education, recreation and leisure time and social relationships (Derek 2009).

Health-related quality of life (HRQL) enables sensitive detection and measurement in clinical trials of important effects on the health of populations and can provide information for policy decisions (Guyatt 1993). Widely valued aspects of life exist that are not generally considered as "health" including income, freedom, and quality of the environment. Although low or unstable income, lack of freedom, or a low-quality environment may severely affect health; these problems are often distanced from a health or medical perspective. Clinicians focus on HQRL, although when a patient is ill or diseased, almost all aspects of life can become important and health related (Derek 2009).

HQRL serves as an index of the impact of the severity of a given health condition (Patrick 1993). The health condition may be less distressing for patients than the loss of functional capacity associated with ill-health, but health problems drastically reduce the individual's sense of well-being and affects their interpersonal relations, resulting in further reduction in well-being, which can lead into depression and exacerbation of existing the health condition. These considerations underlie interest in the QOL of the patients.

6.3 Methods

Full details of the intervention study methodology have been given in previous sections, in brief

6.3.1 Aim

The aim of this study was to assess the effect of TTM-tailored SMS to improve the quality of life of the intervention group

6.3.2 Objectives

- To analyze the difference between control and intervention groups in four dimensions of QOL at baseline.
- To analyze the difference in QOL of the study groups (control and intervention) at the end of the study.
- To analyze the difference in QOL of the study participants according to the educational background.

6.3.3 Research design

This was a 2 year prospective, parallel-group randomized controlled trial in men with IGT. The study consisted of two groups: control (standard care advice) and intervention (frequent TTM tailored SMS).

6.3.4 Statistical method

To analyze the baseline difference in the four dimensions of the quality of life of the study subjects independent sample 't' test was used. One-way ANOVA was used to analyze the difference in QOL according to the educational qualifications of the study subjects.

6.3.5 Participants

The participants were men working in public and private sector industrial units in Southeast India (Chennai, Tamilnadu and Visakhapatnam, Andhra Pradesh) and were screened for eligibility by questionnaire and recruited. The study was conducted in workplace because 96% of the employees were men, and we included only men in this trial. The employees were selected such that they would continue for the full tenure of the study.

6.3.6 Study procedure

This was a prospective, parallel-group, randomized controlled trial lasting two years and comparing two groups: control (standard care advice at baseline) and intervention (frequent TTM tailored SM). The participants were reviewed every six months for two years. The demographic details, anthropometric measurements, biochemical investigations, transtheoretical model (TTM) stages with respect to diet

and physical activity practices, quality of life and general health and diabetes awareness were measured at baseline and reviewed at six monthly intervals.

6.3.7 The intervention

At baseline, all participants received personalized education and motivation about healthy lifestyle principles (to improve physical activity and change unhealthy dietary practices) and individualized written information about diet and physical activity. The prescribed lifestyle recommendations were similar to those used in our previous prevention trial in India (Ramachandran 2006). In addition to standard lifestyle advice, participants in the intervention group received mobile phone SMS at frequent intervals. These SMS contained information about healthy lifestyle, the benefits of physical activity and diet, cues to start physical activity and healthy dietary practices, and strategies to avoid relapse and remain motivated to maintain physical activity and healthy dietary habits. The content of the SMS at anytime was based on the transtheoretical model of behavior change.

6.3.8 Tool used

In this study, the following tools were used:

1. The TTM stages of change inventory to assess the study participants TTM stages with respect to physical activity and dietary habits.

2. SMS acceptability grade

3. The World Health Organization Quality Of Life – BREF (WHOQOL-BREF) questionnaire (WHOQOL-BREF 1998).

4. The general health and diabetes awareness questionnaire (Murugesan 2007).

In this chapter the data on quality of life alone is analysed and discussed. A detailed description of the WHOQOL-BREF questionnaire (previously summarised in chapter 2) is given in the following section.

6.3.8.1 WHOQOL-BREF questionnaire

The WHOQOL-BREF questionnaire (WHOQOL-BREF 1998) aims to assess the individuals' perceptions on the quality of their life. The WHOQOL-BREF is a shorter version of the original instrument the WHOQOL-100 (The WHOQOL Group 1994a; 1994b) and aims to provide a broad and comprehensive assessment, with one item from each of the 24 facets contained in the WHOQOL-100. In addition, two items from the overall QOL and general health facet have been included in the WHOQOL-BREF. The questionnaire assesses four domains of quality of life and each domain assesses certain specific facets of the person's life. The four domains are: 1) the physical capability (activities of daily living, dependence on medicinal substances and medical aids, energy and fatigue, mobility, pain and discomfort, sleep and rest and work capacity); 2) psychological (bodily image and appearance, negative feelings, positive feelings, self-esteem, spirituality/ religion/ personal beliefs and thinking, learning, memory and concentration); 3) Social relationships (personal relationships, social support and sexual activity); and 4) environmental aspects of quality of life of the study subjects (financial resources, freedom, physical safety and security, health and social care: accessibility and quality, home environment, opportunities for acquiring new information and skills, participation in and opportunities for recreation/ leisure activities, physical environment (pollution/ noise/ traffic/ climate and transport). The questionnaire is standardized for an adult population.

The WHOQOL-BREF is more convenient for use in large research studies or clinical trials (Murphy 2000). Its psychometric properties were analysed using cross-sectional data from 23 countries including Chennai, India (Skevington 2004). Among Indian languages, it has been translated into Hindi, Tamil and English (Saxena 1998). Sick and healthy respondents were sampled from general population, as well as from hospitals, rehabilitation and primary care settings. Patients with physical or psychological disorders or with important socio-demographic characteristics were also sampled. Analyses of internal consistency, item-total correlations, discriminant validity and construct validity through confirmatory factor analysis indicate that the WHOQOL-BREF has good to excellent psychometric reliability and performs well in preliminary tests of validity.

WHOQOL-BREF comprises 26 items with 5 point rating scale responses starting from strongly disagree, then to disagree, neither disagree nor agree, agree and strongly agree (score ranged 1 – 5). The 26 items are categorized in to 4 domains, 7 items for assessing the physical capability, 6 items for assessing psychological QOL. The social relationship is assessed with 3 items and the environmental domain is assessed using 8 items. There are two items that are examined separately: question 1 asks about an individual's overall perception of quality of life and question 2 asks about an individual's overall perception of their health. The four domain scores denote an individual's perception of quality of life in each particular domain. Domain scores are scaled in a positive direction (i.e. higher scores denote good QOL, low scores refers to poor QOL). There are 3 negatively phrased items (3, 4 and 26) scored in reverse order. The maximum score for each domain are: physical – 35, psychological – 30, social – 15, environmental – 40.

The WHOQOL-BREF item number and facets in each domain is shown in section 2, in table 2.4.

6.3.8.2 Questionnaire administration

The WHOQOL-BREF is a self-administered questionnaire if respondents have sufficient ability to follow the standardized instructions: otherwise, the questionnaire is interviewer-assisted or interviewer administered, with the interviewer reading out the instructions and questions on QOL. A time limit of two weeks was given to respondents to recall the incidents related to the questions to be answered.

6.3.8.3 Proposed uses of the WHOQOL-BREF questionnaire

It was anticipated that the WHOQOL-BREF assessments would be used in broad-ranging ways including in clinical trials to establish baseline scores in a range of areas, and to identify changes in QOL in the course of interventions. It is expected that the WHOQOL assessments will also be of value where disease prognosis is likely to involve only partial recovery or remission, and where treatment may be more palliative than curative.

6.4 Results

6.4.1 Quality of life among the study groups at baseline

Quality of life score were compared between the randomized study groups using independent sample "t" test (table 6.1). The intervention group had higher quality of life in social relationship (p=0.005). No significant difference was observed between the two groups in physical, psychological and environmental quality of life.

Table 6.1. Comparison of scores on quality of life between control and intervention group at baseline

Quality of life (scores)	Control (266)	Intervention (271)	P value
Physical	26.7 ± 2.7	27.2 ± 2.9	NS
Psychological	21.4 ± 2.5	21.6 ± 2.9	NS
Social	11.8 ± 1.4	12.2 ± 1.5	0.005
Environmental	29.5 ± 2.9	29.8 ± 3.3	NS

Independent sample "t" test was used, mean and standard deviation are given

6.4.2 Quality of life at baseline and at the end of study

The baseline and end of the study quality of life scores of the total study group were compared using paired 't' test. The participants significantly improved in psychological quality of life (t=-2.094; p<0.037).

Table 6.2. Comparison of quality of life score of the total study group (n=517) at baseline and at the end of the study. Data are mean ± SD.

Quality of life	Maximum score	Scores		p value
		Baseline	End of the study	
Physical	35	27.03 ± 2.86	26.96 ± 3.09	0.549
Psychological	30	21.58 ± 2.75	21.82 ± 2.67	0.037
Social	15	12.06 ± 1.53	12.02 ± 1.46	0.522
Environment	40	29.74 ± 3.17	29.64 ± 3.15	0.452

Paired 't' test was used

6.4.3 Change in quality of life scores within the study groups

Intra-group variation in quality of life was analysed in the control and intervention groups, as shown in table 6.3. The control group did not shown any improvement in any of the four domains of quality of life, the intervention group significantly improved in psychological quality of life (t=-2.206; p<0.028) at the end of the study.

Table 6.3. Intra group comparison of quality of life scores at baseline and at the end of study in the control and intervention groups. Data are mean ± SD

Quality of life	Scores			
	Control (n=256)		Intervention (n=261)	
	Baseline	End of the study	Baseline	End of the study
Physical	26.79 ± 2.75	26.74 ± 3.03	27.27 ± 2.95	27.17 ± 3.14
Psychological	21.51 ± 2.60	21.63 ± 2.62	21.64 ± 2.90	22.02 ± 2.72*
Social	11.88 ± 1.49	11.89 ± 1.51	12.25 ± 1.55	12.15 ± 1.39
Environment	29.58 ± 2.95	29.59 ± 3.10	29.90 ± 3.37	29.68 ± 3.21

Paired 't' test was used, *p=0.028

6.4.4 Difference in quality of life between study groups

Table 6.4 showing the Inter group comparison at baseline and end of the study, with significant differences identified using student 't' test. At baseline the groups differed significantly only in social quality of life (t=2.735; p=0.006). The significant difference continued till the end of the study (t=2.026; p=0.043).

Table 6.4. Inter group comparison of quality of life scores between control and intervention groups at baseline and at the end of study. Data are mean ± SD

Quality of life	Scores			
	Baseline		End of the study	
	Control (n=256)	Intervention (n=261)	Control (n=256)	Intervention (n=261)
Physical	26.79 ± 2.75	27.27 ± 2.95	26.74 ± 3.03	27.17 ± 3.14
Psychological	21.51 ± 2.60	21.64 ± 2.90	21.63 ± 2.62	22.02 ± 2.72
Social	11.88 ± 1.49	12.25 ± 1.55**	11.89 ± 1.51	12.15 ± 1.39*
Environment	29.58 ± 2.95	29.90 ± 3.37	29.59 ± 3.10	29.68 ± 3.21

Student 't' test was used. **p=0.006, *p=0.04

6.4.5 Difference in quality of life domains between three diagnostic categories

Change in quality of life from baseline to follow up between participants completing follow up in one of the three diagnostic groups (NGT, IGT & DM) was analysed using one way ANOVA (table 6.5). Except for social quality of life ($p<0.05$), the three diagnostic groups did not differ in any of the four domains of quality of life. Post hoc comparisons sowed that the subjects who had developed diabetes by the end of study scored less in social quality of life at baseline ($p<0.05$).

Table 6.5. Change in the quality of life domains in the three diagnostic categories at the end of the study. Data are mean ± SD.

Quality of life	Scores					
	NGT (n=170)		IGT (n=224)		DM (N=123)	
	Baseline	End of study	Baseline	End of study	Baseline	End of study
Physical	27.09 ± 2.95	26.98 ± 3.15	27.02 ± 2.87	26.92 ± 3.06	26.98 ± 2.74	27.00 ± 3.09
Psychological	21.61 ± 3.04	21.98 ± 2.66	21.64 ± 2.67	21.84 ± 2.64	21.42 ± 2.48	21.58 ± 2.76
Social	12.28 ± 1.55	12.12 ± 1.37	12.01 ± 1.43	11.99 ± 1.51	11.85 ± 1.66*	11.93 ± 1.48
Environment	29.94 ± 3.40	29.52 ± 3.33	29.73 ± 3.17	29.66 ± 3.20	29.50 ± 2.84	29.76 ± 2.80

One way ANOVA was used, * Baseline NGT Vs IGT Vs DM $p<0.05$

[(Normal glucose tolerance (NGT), Impaired Glucose Tolerance (IGT), and Diabetes mellitus (DM)]

6.4.6 Influence of educational qualification on the quality of life

The physical, psychological, social and environmental quality of life of the study subjects at baseline were analysed in relation to their educational qualification. The results (table 6.6) showed that, there was a significant variation in physical ($p<0.023$), psychological ($p<0.001$) and environmental ($p<0.007$) quality of life with respect to their educational qualification. Subjects' did not differ in social quality of life. Subjects with a professional qualification showed better quality of life in physical, psychological and environmental domains followed by participants who have completed college education, as compared to the two other groups. Post-hoc comparisons showed that participants with a professional qualification scored high compared with technical qualification participants in physical ($p=0.012$) and psychological ($p<0.0001$) domains. Professionally qualified participants differed significantly with participants from school education ($p=0.005$) and technically qualified subjects ($p=0.030$).

Table 6.6. Quality of life among the study subjects with regard to educational qualification at baseline

Quality of life (scores)	Educational qualification				P value
	School (91)	College (90)	Technical (249)	Professional (107)	
Physical	26.89 ± 2.74	27.01 ± 3.04	26.74 ± 2.81	27.76 ± 2.92	0.023
Psychological	21.63 ± 3.02	21.51 ± 2.91	21.14 ± 2.57	22.44 ± 2.64	0.001
Social	12.09 ± 1.61	11.98 ±1.59	12.04 ± 1.52	12.21 ± 1.39	NS
Environmental	29.09 ± 3.14	29.62 ± 3.29	29.57 ± 3.23	30.58 ± 2.85	0.007

Mean ± S.D. are shown

6.5 Discussion

At the baseline the study groups were homogeneous in their QOL scores for physical capability, psychological and environmental quality of life. At the end of the study the participants showed significant improvements in psychological QOL and significant improvement was observed in the intervention group in psychological QOL. It was noted that at baseline the intervention group had good QOL in the social relationships domain, and the difference continued till the end of the study. It was worth noting that at the end of the study physical activity was not improved with SMS intervention in the intervention group but healthy dietary change was achieved by the intervention group. (Ramachandran 2013) There are no studies which show that improvement in dietary habits helps to improve QOL, but in our study the intervention group significantly improved their dietary habits which might have contributed to general wellbeing and consequently QOL.

One study (Kolotkin 2001) has shown that weight reduction helped to improve QOL among prediabetic subjects but, in this study, improvement in QOL was achieved independent of weight loss. Other studies (Jacobson 2004; Marcia 1998) have shown that glycemic benefit can be associated with improvement in QOL. This suggests that the glycemic improvement achieved by the intervention group in the present study could have helped in improvement in QOL.

There is evidence that, as might be expected, very obese people have very poor QOL (Ruth Kalda 2008). In the present study, though the majority of the participants were obese, they were not highly obese, which could have contributed to relatively good QOL at baseline. At baseline, participants were not affected by any chronic disease like diabetes, heart disease and arthritis hence, their QOL was further likely to be good; nevertheless, and intervention helped to improve their QOL further.

Physical, psychological, social and environmental aspects of QOL were analysed in relation to educational qualification. The groups significantly differed in physical, psychological and environmental QOL. Educational background did not contribute to social QOL. Participants with professional qualification had better QOL than the other three groups. This is similar to the findings of two other studies (Glasgow 1997; Issa 2006) that have shown that lower education level adversely affects the QOL of the participants. This finding is vital because education is an essential factor in understanding self-care and management of diabetes, glycaemic control, and perception of self-worth.

The subjects did not differ in physical, psychological and environmental QOL based on their glycemic status at the end of the study (normal glucose tolerance, IGT and diabetes). The subjects who converted to diabetes at the end of follow up had a low social quality of life score compared with those who converted to normal glucose tolerance. This could be due to the present health condition of the diabetic subjects. This finding contrasts with an earlier study (Robyn 2006) which showed a gradual decrease in quality of life across categories of glucose tolerance status. This could have been due to the effect of participation in the diabetes prevention programme.

6.6 Conclusion

The participation in the diabetes prevention trial helped to improve the psychological QOL of the study subjects but SMS intervention helped to improve the QOL of the subjects significantly in the intervention group. SMS did not have an impact in improving the social QOL. Educational qualification has a significant role in improving the QOL of the study subjects.

SUMMARY OF THE MAIN FINDINGS

7.1 Impact of TTM-based SMS on incidence of type 2 diabetes

This is the first trial to demonstrate TTM tailored SMS is an effective intervention strategy in the primary prevention of T2D (Ramachandran 2013). The SMS were generally well accepted. The proof of principle has therefore been established that SMS is an effective intervention tool to reduce the incidence of T2D. We aimed to induce lifestyle changes (healthy dietary practices and improved physical activity) through motivating SMS. The SMS was associated with reduced dietary energy consumption on recall. No significant difference was observed between the study groups in physical activity level and body weight. The beneficial impact of SMS on glycaemia was observed in the first six month.

7.2 Impact of TTM based SMS on shift in TTM stages

In our study, at baseline a small proportion (12% - 14%) of subjects were in the precontemplation stage with regard to diet and physical activity practices, indicating that some participants were unaware of the benefits of healthy diet practices. The majority of the participants were in the contemplation stage and were aware of the benefits of healthy lifestyle and intended to change in the next six months. Approximately 19% of the participants were in the action and maintenance stage. Overall a large proportion of subjects were in the pre-action stage and only very small numbers were in the action phase and were following healthy lifestyle. At the end of the study no participant relapsed to the precontemplation stage, with the majority of the subjects shifting to action phase. The shift in TTM stages is reflected in the conversion rate to diabetes. Diabetes prevention was significantly more apparent in participants in the action phase. This could have been due to several

factors including awareness creation and personalized education on diabetes and other chronic diseases, and on the benefits of healthy lifestyle through SMS. This was a novel observation not previously reported in other behavioral studies that had used TTM theory for tailoring intervention. In our study healthy dietary practices were sustained for 24 months, although the changes were seen already after a year of intervention. Continuous motivation and education via TTM-staged SMS helped to produce sustained behavioral change which likely contributed to the significant reduction in the incidence of diabetes

The baseline physical activity practices with respect to TTM stages were similar in both groups, but significant shifts in TTM stages were observed in the first six months in the intervention group. Significantly more participants shifted from pre-action to action stage. However, the trend did not continue to the end of the study despite constant motivating reminders by SMS to improve physical activity. This could be due to the fact that, our study participants were industrial workers, the majority of whom were skilled workers involved in strenuous activity, hence they were not able to do additional physical activity. Secondly majority of the participants were working in a shift system, which might have disrupted or intervened participants in adapting regular physical activity practices. Previous diabetes prevention studies which showed improvement in physical activity had used personal contact, individual counselling, and supervised intervention with the participants. Therefore, more intensive approaches than SMS based motivation may be needed to produce sustained improvement in physical activity. The analysis showed that, change in dietary habits helped to reduce the incidence of T2D which was achieved independently of weight loss.

7.3 Impact of healthy lifestyle SMS on awareness level on general health and diabetes

This is the first trial to demonstrate the effect of SMS intervention in improving the awareness level of the participants. The level of awareness on general health and diabetes at baseline in both the groups were similar. SMS on healthy lifestyle and diabetes helped the intervention group to improve their level of awareness. Awareness on diabetes was significantly higher among those who had a positive family history. Subjects with a history of hypertension had significantly higher awareness on general health than subjects with no history of hypertension. The diabetes awareness level did not differ in these groups. This indicates that people with hypertension are not aware of the fact that hypertension and diabetes are commonly associated. Hence, it is necessary to educate and create more awareness programmes on diabetes in people with hypertension. Educational qualification had a significant impact on awareness level. The awareness level on general health and diabetes increased with higher level of education.

It was also found that the awareness level differed according to the glycaemic categories at the end of the study. Higher awareness level was observed in people who developed normal glucose tolerance and remained IGT compared to subjects who developed diabetes.

7.4 Impact of awareness level on quality of life at the end of the study

At baseline the groups were homogeneous in physical, psychological and environmental quality of life. The intervention group had significantly higher scores in social quality of life than control group and this difference continued till the end of the

study. Psychological quality of life improved significantly in the intervention group participants. The quality of life increased with higher levels of education.

7.5 Limitations

Our study has certain limitations. Firstly, the trial included only working men, as a consequence of the industrial organizations which agreed to participate employing mostly (96.3%) men. Women's responses and reactions to text messages might differ from those of men, but we had recruited insufficient women to assess gender effects. Hence, the efficacy and acceptability of SMS in women, and amongst other groups of men, needs to be addressed in future studies. Secondly, the setting was an urban population in India. The application of text messaging to other populations also needs to be studied. Finally although our methodology attempted to minimize bias, the field workers were by necessity not blinded and we cannot exclude the possibility of bias, however unlikely, at this level.

We have used the transtheoretical model in our study as a basis for the LSM strategy. Although this model has a considerable evidence base, it is not uniformly accepted and we cannot be sure of its importance in this trial as other behavioral theories were not studied. Moreover, in this trial, it was not possible to separate the effects of SMS per se from the contribution of TTM message tailoring. Such a demonstration would have required a further group receiving standard, un-tailored text messages. To justify such a study, however, it was first necessary to prove the principle that a high quality of SMS intervention could help prevent diabetes.

7.6 Overall Conclusion

Significant improvement in diet, physical activity and many other behaviors, could lead to considerable benefit for the individual and for society as well. However, there is a constant challenge to find effective ways to change behaviors to promote health and prevent disease and improve health outcomes. The participants in this study found the SMS intervention that delivers daily evidence-based messages acceptable and overall useful in the continued response phase of the behavior change process. The TTM tailored text message is an effective and acceptable communication tool for educating and motivating people with IGT to change unhealthy dietary practices in order to prevent or delay the onset of type 2 diabetes. One message per day and up to three messages per week was the optimal delivery frequency and a message before 8:00 A.M. and after 5:00 P.M. was the preferred timing. Overall, the cumulative incidence of type 2 diabetes was lower in those who received mobile phone messages than in controls: 50 (18%) participants in the intervention group developed type 2 diabetes compared with 73 (27%) in the control group. The number needed to treat to prevent one case of type 2 diabetes was 11 (95% CI 6–55). There was no significant effect of the intervention on BMI, waist circumference, blood pressure, or serum cholesterol and triglycerides, but the effect on HDL cholesterol was significant. Total dietary energy intake was lower in the intervention group than in the control group, whereas physical activity scores did not differ.

Consistent with the literature that suggests people are more sensitive to prevention strategies in the later stages of the behavior change process (Rothman et al., 2004), prevention-based diet messages were more useful in helping participants to sustain healthy diet practices. However, the strategy was not successful in enhancing people who are physically active in their job. Alternative strategies need to be developed in

terms of content of method. Finally, technological tools such as tailored SMS intervention that are constructed and guided by evidence-based content and theoretical constructs show promise in helping people sustain healthy diet behavior that can lead to improved health outcomes. The intervention improved the awareness level on general health and diabetes. Notably, adherence to healthy diet practices accompanied improvement in the psychological quality of life of the participants.

7.7 Health policy implications

As the world takes note of the escalating rates of NCDs, we know that a substantial proportion of type 2 DM and its complications is preventable, if current evidence-based interventions can be systematically implemented.

The most pressing need in India currently is the primary prevention of diabetes. Screening for glucose intolerance as a preventive measure, even in those younger than 30 years of age, is a requisite in Asian Indians because they develop diabetes at a very young age. Cost-effective and sustainable interventions that can be translated in real-life settings for the prevention and control of diabetes are needed. Interventions must also have the potential to be put into clinical practice in a range of settings, be low in cost, and widely disseminated to people with diabetes and their communities.

Systematic randomized controlled prospective diabetes prevention trials conducted in different parts of the world demonstrate that change in lifestyle reduces the incidence of type 2 diabetes in participants with impaired glucose tolerance. However, the translation of these findings into the real world setting or in the community at large has been difficult due to the limited resources of health care professionals such as nurses, registered dieticians, exercise physiologists, volunteer medical personnel and YMCA trainers who were part of the previous diabetes prevention programs. Multiple

personal contacts were made by these health care professionals to motivate participants to follow healthy lifestyle throughout the study period. The DPS and DPP study had used structured educational and exercise programme for weight reduction, whereas, in the present study, personal contacts were made for recruitment and review of the participants and to collect the necessary data regarding demographic details, behavioural practices (diet and physical activity), and work related information and also for giving standard care advice only at baseline; moreover no further personal contacts were made to motivate participants to follow healthy lifestyle.

The rationale behind the application of SMS interventional strategy was to motivate participants to follow healthy lifestyle advices throughout the study period. India has limited resources of qualified and trained personnel in health research to counsel or train people to follow healthy lifestyle. Therefore, it was aimed to develop an alternative strategy for personal motivation and maximise the effectiveness of human intervention.

This study has demonstrated that TTM tailored SMS was effective in the prevention of T2DM in people with IGT. The study had shown that behavioural theory-based SMS was effective in changing the unhealthy dietary practices of the participants' i.e. sustained healthy dietary practices such as decrease in portion size (total energy intake) followed by decreased consumption of oil. The study also demonstrated that TTM tailored SMS was effective in changing the sedentary lifestyle of the participants in the first six months and the change was not sustained throughout the study period. The probable reason for withdrawal of active behavior after the first six months could be, the participants enrolled in this diabetes prevention programme were industrial workers and amongst this 64% of the participants were skilled workers involved in strenuous work related to their job.

Another important finding of this research was that only 3% of the participants felt the SMS was disturbing them, all others participants felt happy with the content, frequency, and timing of the SMS. In general the participants felt the SMS was very useful and well accepted method to lead a healthy lifestyle to prevent diabetes.

The findings of this research has paved the way for translating the theory-based SMS strategy for the prevention and management of other lifestyle diseases like, hypertension, cardiovascular diseases, stroke and other high risk conditions such as overweight or obesity, and unhealthy behaviors like physical inactivity, unhealthy diet practices and smoking cessation. Since diabetes, hypertension and cardiovascular diseases carry similar modifiable and non-modifiable risk factors and are linked to each other for the development of the diseases, similar healthy behavior is needed for the prevention of the diseases. The SMS strategy with similar educational and informative messages can be very well applied for the prevention and management of all lifestyle diseases.

Many government and public health decision makers remain largely unaware of the magnitude, or, more importantly, of the future burden for increase in diabetes and its serious complications in their respective countries. The looming negative economic impact of this disease on individuals, on families, on organization and on national economy is alarming.

We believe that Government and Non-Government organizations have a responsibility to implement proven strategies and evaluate them in real world settings through translational research. Translational research is defined as the mechanism to transform currently available knowledge into useful measures for everyday clinical and public health practice (Narayan K, Benjamin E, 2004). Translational research aims to assess implementation of standards of care, understand the barriers to their

implementation, and intervene throughout all levels of health care delivery and public health to improve quality of care and health outcomes, including quality of life. Translational research is addressing one of the main challenges of today's medical and educational world: closing the fast growing gap between scientific knowledge and effective health care strategies that improve diabetes outcomes.

Concerted efforts by governmental and non-governmental agencies with structured national programs for control and prevention of diabetes and other NCD's are warranted in all countries, especially in countries with limited health care resources.

7.8 Recommendations for future research

The majority of the studies have shown the effectiveness of mobile technology in prevention and management of communicable and non-communicable diseases. However, the major limitation in the application of SMS technology in this population is that, although ownership of mobile phone enables participation in a health intervention study or receipt of health information, it is not possible to enroll all individuals who own a mobile phone in SMS intervention or awareness raising or health education programmes. The reason is that, in India not all the individuals who own a mobile phone can read and understand the SMS if the individual does not have a formal education qualification: there is still a small percentage of people using mobile phones just to make and receive calls. This issue highlights the need for traditional educational methods, including educating people on a one-to-one basis, doctor patient counselling, group counselling or group education.

Secondly, India being a country of diversity in caste, community, religion, language, culture, dietary practices and socio-economic condition, it is very much important to consider the diet pattern and the nature of work (sedentary or strenuous work) and educational background of the participant for the implementation of the SMS

strategy. India has more than 100 languages in use. Every region has their own unique language which is called their mother tongue, spoken by the majority of the people living in that region. The content of the SMS used in these studies was developed in English in a very short and simple manner (less than 168 characters) which is very easy to understand. The basic mobile phones do not have the compatibility to accept regional languages other than English. Delivery of SMS in regional language would have made understanding the SMS content easier than receiving SMS only in English.

From the literature it was found that mobile phone SMS strategy was used in various disease control measures like malaria, breast cancer, HIV etc. however this strategy was not applied in diabetes prevention in India and also for other NCD's. This study has demonstrated the influence of SMS text messaging in diabetes prevention. Therefore this method can be well implemented for diabetes prevention and other lifestyle related diseases.

There are many other features of the mobile phone that may be just as or even more beneficial. These include two-way interactive communication, video and picture messages, mobile applications or 'Apps', geospatial tracking, social networking, and many others. The nature of this intervention was not interactive, it only involved participants simply reading a health message. Though this added an element of simplicity, a more interactive intervention, where participants could receive daily tailored feedback on their diet and exercise, based upon information they enter into a mobile application, could have improved behavior change and increased benefits more.

The findings of this research suggest that more prospective, randomized controlled trials are warranted to demonstrate the effects of the tailored SMS intervention. More longitudinal studies with a larger sample size and more diverse populations in diverse

settings that examine the effects of this intervention on diet, exercise, and other common co-morbidities associated with diabetes would provide more conclusive results about the effects of this intervention. A post-trial follow-up would also help to determine whether this intervention helps people transition from a state of pre action to action and from action to maintenance. Interactivity and responsiveness to participants' needs, a potential feature of SMS-delivered interventions, may improve the outcomes of behavior change interventions.(Atkinson NL, Gold RS 2002) One study (Marquez Contreras E, Figuera von Wichmann M 2004) did not allow interaction with participants, and that study had poor participant retention, which may have been associated with poor participant engagement. However it is difficult to quantify the interactivity because of the potential influence of other forms of interaction with participants (e.g., websites). The effect of interactivity of SMS-delivered interventions needs to be explored further to determine the optimal level of interaction for successful behavior change.

Further analysis on cost-effectiveness of this SMS intervention is needed to show the economic benefit of this strategy. Further research is also needed to examine how more comprehensive and interactive SMS can be developed and leveraged to improve primary and secondary prevention of diabetes. . Research involving mobile phone applications is currently ongoing, with the wide spread availability of smart phones and mobile gadgets such as tablets and iPads, an application or "app" could be utilized as a dynamic intervention medium to deliver health care information to promote self-management. Mobile phone applications have various communication facilities. These include, self-record keeping, auto monitoring, customizable auto-feedback, and direct communication to and from a provider and these methods could be used as a tool to health care.

Therefore, these findings may serve as a reference to design future interventions to help people to move from pre-action to action, to prevent relapse and transition from

a state of action behavior to a stage of maintenance. Future research warrants adding and evaluating behavioral theories to action and maintenance of behavior change. Application of the theories to change in diet and physical activity in diabetes prevention are very limited. It is feasible to frame theory based SMS messages focused towards diabetes prevention through healthy diet and improved physical activity changes to fit participants' needs, which could enhance acceptance of the SMS. Results indicated that the group received prevention messages had a greater success in preventing diabetes compared to the control group.

Considering the widespread usage and applications of mobile phones in health research, there is an immediate need to implement the mobile health strategy to face the challenge of translating the evidence on preventive initiatives into affordable and feasible programs in order to curb the diabetes epidemic.

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INDIAN DIABETES PREVENTION PROGRAMME – 3

(UKIERI – IDRF)

India Diabetes Research Foundation & Dr. A. Ramachandran's Diabetes Hospitals

No. 28, Marshalls Road, Egmore, Chennai-600 008. Ph: 044-2858 2003 / 04 / 05

Transtheoretical model physical activity stage inventory (Appendix-1)

Regular exercise is any planned physical activity (e.g. brisk walking, aerobics, jogging, bicycling, swimming, etc.) performed to increase physical fitness. Such activity should be performed 3 to 5 times per week for 20-60 minutes per session. Exercise does not have to be painful to be effective but should be done at a level that increases your breathing rate and causes you to break a sweat. Kindly make a tick in the relevant option if you have been practicing (the response could be one or more).

1. Are you aware of the benefits of exercise or physical activity?
   Yes / No

2. If Yes, what are the benefits?
   a. Reduced weight
   b. Prevents diabetes and heart disease
   c. Prevents hypertension
   d. Prevents all lifestyle disease

3. Presently are you doing any regular exercise?
   Yes / No
4. If Yes, what are the regular exercise you do?
   a. Walking
   b. Household chores
   c. Jogging / Running
   d. Indoor games
   e. Yoga
   f. Cycling
   g. Climbing stairs
   h. Manual labour
   i. Gym exercise
   j. Others, specify
   k. Don't know

5. If No, are you planning to start doing exercise in near future?
   Yes / No

6. If Yes, after how many weeks or months you are planning to start?
   a. After 2 weeks
   b. After 1 month
   c. After 6 weeks
   d. After 2 months

7. How many hours of physical activity is good for a person?
   a. Less than 30 minutes per day
   b. 30 minutes to 1 hour per day
   c. More than 1 hour per day

8. How many hours of physical activity you do in a day?
   a. Less than 30 minutes per day
   b. 30 minutes to 1 hour per day
   c. More than 1 hour per day

9. Since how long you have been practicing exercise?
   a. 1 – 6 months
   b. 7 months to 1 year
   c. 1 year to 2 year
   d. More than 2 year

10. You were doing exercise and not able to continue due to any of the following reason?
    a. Health reason
    b. Lack of time
    c. Official reason
    d. Personal / family commitment
    e. Climatic condition
    f. Any other reason

Transtheoretical model diet stage inventory (Appendix-2)

Healthy diet practice is a planned and modified eating behavior. Below are a few diet practices which people follow in their daily life to be fit and healthy. A healthy diet practice does not mean that you should starve to be fit and healthy. Kindly make a tick in the relevant options if you have been practicing (the response could be one or more).

1. Are you aware of the benefits of diet control
   Yes / No

2. If Yes, what are the benefits?
   a. Reduces / maintain weight
   b. Prevents diabetes / hypertension
   c. Keep fit and healthy
   d. Prevents aging

3. Are you under diet control?
   Yes / No

4. If Yes, what are the different ways of diet control you practice?
   a. Fasting or skipping meal
   b. Reducing quantity of main food
   c. Avoiding rice items
   d. Eating only tiffen items
   e. Avoiding fried foods

5. If No, are you planning to start diet control in near future?
   Yes / No

6. If Yes, after how many weeks or months your are planning to start diet control?
   a. After 2 weeks
   b. After 1 Months
   c. After 6 weeks
   d. After 2 Months

7. Do you know the good method or diet control?
   Yes / No

8. If Yes, what are the good method of diet control?
    a. Eating lot of vegetables
    b. Taking snacks or oil stuff foods
    c. Whole cereals
    d. Timely meals
    e. Eating only chappathy or roti
    f. Eating only tiffen items
    g. Don’t know

9. If you are under diet control, following any of the above, since how long you have been following?
    a. Last one month
    b. Last six month
    c. Last one year
    d. More than one year

10. Were you under diet control and not able to continue due to any of the following reason
    a. Household works
    b. Financial reason
    c. Personal/ family commitment
    d. Family size
    e. Any other reason

INDIAN DIABETES PREVENTION PROGRAMME – 3

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Transtheoretical model physical activity stage inventory scoring key (Appendix-3)

Regular exercise is any planned physical activity (e.g. brisk walking, aerobics, jogging, bicycling, swimming, etc.) performed to increase physical fitness. Such activity should be performed 3 to 5 times per week for 20-60 minutes per session. Exercise does not have to be painful to be effective but should be done at a level that increases your breathing rate and causes you to break a sweat. Kindly make a tick in the relevant option if you have been practicing (the response could be one or more).

1. Are you aware of the benefits of exercise or physical activity?

   Yes (**Yes refers to any one among these four stages; contemplation, preparation, action or maintenance stage**)

   No (**No refers to precontemplation stage**)

2. If Yes, what are the benefits?
   a. Reduced weight
   b. Prevents diabetes and heart disease
   c. Prevents hypertension
   d. Prevents all lifestyle disease

   (**Lie scale**)

3. Presently are you doing any regular exercise?

   Yes (**Yes refers to action or maintenance stages**)

   No (**No refers to contemplation or preparation stages**)

4. If Yes, what are the regular exercise you do?
    a. Walking
    b. Household chores
    c. Jogging / Running
    d. Indoor games
    e. Yoga
    f. Cycling
    g. Climbing stairs
    h. Manual labour
    i. Gym exercise
    j. Others, specify
    k. Don't know

    (**Lie scale**)

5. If No, are you planning to start doing exercise in near future?

    Yes (**Yes refers to contemplation or preparation stages**)

    No (**No refers to precontemplation stage**)

6. If Yes, after how many weeks or months you are planning to start?

    a. After 2 weeks
    b. Within 1 month

    (**Option a & b refers to preparation stage**)

    c. After 6 weeks
    d. After 2 months

    (**Option c & d refers to contemplation stage**)

7. How many hours of physical activity is good for a person?
    a. Less than 30 minutes per day
    b. 30 minutes to 1 hour per day
    c. More than 1 hour per day

    (**Lie scale**)

8. How many hours of physical activity you do in a day?
    a. Less than 30 minutes per day
    b. 30 minutes to 1 hour per day
    c. More than 1 hour per day

    (**Lie scale**)

9. Since how long you have been practicing exercise?

    a. 1 – 6 months **-** (**Option a refers to action stage**)

    b. 7 months to 1 year
    c. 1 year to 2 year
    d. More than 2 year

    } (**Option b, c and d refers to maintenance stage**)

10. You were doing exercise and not able to continue due to any of the following reason?

    a. Health reason
    b. Lack of time
    c. Official reason
    d. Personal / family commitment
    e. Climatic condition
    f. Any other reason

    } (**Lie scale**)

Transtheoretical model diet stage inventory scoring key (Appendix-4)

Healthy diet practice is a planned and modified eating behavior. Below are a few diet practices which people follow in their daily life to be fit and healthy. A healthy diet practice does not mean that you should starve to be fit and healthy. Kindly make a tick in the relevant options if you have been practicing (the response could be one or more).

1. Are you aware of the benefits of diet control

   Yes (**Yes refers to any one among these four stages; contemplation, preparation, action or maintenance stage**)

   No (**No refers to precontemplation stage**)

2. If Yes, what are the benefits?
   a. Reduces / maintain weight
   b. Prevents diabetes / hypertension
   c. Keep fit and healthy
   d. Prevents aging

   } **Lie scale**

3. Presently are you under diet control?
   Yes (**Yes refers to action or maintenance stage**)

   No (**No refers to contemplation or preparation stage**)

4. If Yes, what are the different ways of diet control you practice?
   a. Fasting or skipping meal
   b. Reducing quantity of main food
   c. Avoiding rice items
   d. Eating only tiffen items (light food)
   e. Avoiding fried foods

   } **Lie scale**

5. If No, are you planning to start diet control in near future?
   Yes (**Yes refers to contemplation or preparation stage**)

   No (**No refers to precontemplation stage**)

6. If Yes, after how many weeks or months you are planning to start diet control?
   a. After 2 weeks
   b. Within 1 Month

   } (**Option a & b refers to preparation stage**)

   c. After 6 weeks
   d. After 2 Months

   } (**Option c & d refers to contemplation stage**)

7. Do you know the good method or diet control?

   Yes - (**Any of the four stages**)

   No - (**No refers to precontemplation stage**)

8. If Yes, what are the good method of diet control?
   a. Eating lot of vegetables
   b. Taking snacks or oil stuff foods
   c. Whole cereals
   d. Timely meals
   e. Eating only chappathy or roti
   f. Eating only tiffen items
   g. Don't know

   } **Lie scale**

9. If you are under diet control, following any of the above, since how long you have been following?
   a. 1 - 6 months - (**Option a refers to action stage**)

   b. 7 months to 1 year
   c. 1 year to 2 year
   d. More than two year

   } (**Option b, c and d refers to maintenance stage**)

10. Were you under diet control and not able to continue due to any of the following reason
    a. Household works
    b. Financial reason
    c. Personal/ family commitment
    d. Family size
    e. Any other reason

    } (**Lie scale**)

INDIAN DIABETES PREVENTION PROGRAMME – 3

(UKIERI – IDRF)

India Diabetes Research Foundation & Dr. A. Ramachandran's Diabetes Hospitals

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SMS Acceptability questionnaire (Appendix-5)

Given below are a few questions related to the SMS you receive, kindly give your valuable responses and comments to improve our services.

S. No.	QUESTIONS	Yes	No
1	Are you happy with the SMS?		
2	Are you happy with the frequency of SMS?		
3	Do you find it difficult to understand the SMS?		
4	Do you want us to increase the frequency of SMS?		
5	Do you feel the SMS helps improve to your health?		
6	What is your preferred time to receive SMS?		
7	Do you feel the SMS disturbs you?		
8	Do you have any other comments?		

WHO-QOL BREF Quality of life questionnaire (Appendix – 6)

INDIAN DIABETES PREVENTION PROGRAMME-3
(UKIERI-IDRF)
India Diabetes Research Foundation & Dr. A. Ramachandran's Diabetes Hospitals
No.28, Marshalls Road, Egmore, Chennai - 600 008. Ph:044-2858 2003 / 04 / 05

Health Related Self-Concept Questionnaire
(An Aspect of Quality of Life)

The following questions ask how you feel about your quality of life, health or other areas of your life. Read each question and answer in the response options given. **Please choose the answer that appears most appropriate.** If you are unsure about which response to give to a question, the first response you think of is often the best one.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last four weeks.**

Sl. No.		Very Poor	Poor	Neither poor nor good	Good	Very good
1.	How would you rate your quality of life?	1	2	3	4	5

Sl. No.		Very dissatisfied	Dissatisfied	Neither satisfied nor dissatisfied	Satisfied	Very satisfied
2.	How satisfied are you with your health?	1	2	3	4	5

The following questions ask about **how much** you have experienced certain things in the last four weeks.

Sl. No.		Not at all	A little	A moderate amount	Very much	An extreme amount
3	To what extent do you feel that physical pain prevents you from doing what you need to do?	5	4	3	2	1
4	How much do you need any medical treatment to function in your daily life?	5	4	3	2	1
5	How much do you enjoy life?	1	2	3	4	5
6	To what extent do you feel your life to be meaningful?	1	2	3	4	5

Sl. No.		Not at all	A little	A moderate amount	Very much	Extremely
7.	How well are you able to concentrate?	1	2	3	4	5
8.	How safe do you feel in your daily life?	1	2	3	4	5
9.	How healthy is your physical environment?	1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last four weeks.

Sl. No.		Not at all	A little	Moderately	Mostly	Completely
10.	Do you have enough energy for everyday life?	1	2	3	4	5
11.	Are you able to accept your bodily appearance?	1	2	3	4	5
12.	Have you enough money to meet your needs?	1	2	3	4	5
13.	How available to you is the information that you need in your day-to day life?	1	2	3	4	5
14.	To what extent do you have the opportunity for leisure activities?	1	2	3	4	5

Sl. No.		Very Poor	Poor	Neither Poor Nor good	Good	Very good
15.	How well are you able to get around?	1	2	3	4	5

Sl. No.		Very dissatisfied	Dissiatisfied	Neither satisfied nor Dissatisfied	Satisfied	Very satisfied
16.	How satisfied are you with your sleep?	1	2	3	4	5
17.	How satisfied are you with your ability to perform your daily living activities?	1	2	3	4	5
18.	How satisfied are you with your capacity for work?	1	2	3	4	5
19.	How satisfied are you with yourself?	1	2	3	4	5
20.	How satisfied are you with your personal relationships?	1	2	3	4	5
21.	How satisfied are you with your sex life?	1	2	3	4	5
22.	How satisfied are you with the support you get from your friends?	1	2	3	4	5
23.	How satisfied are you with the conditions of your living place?	1	2	3	4	5
24.	How satisfied are you with your access to health services?	1	2	3	4	5
25.	How satisfied are you with your transport?	1	2	3	4	5

The following questions refers to how often you have felt or experience certain things in the last four weeks.

Sl. No.		Never	Seldom	Quite often	Very often	Always
26.	How often do you have negative feelings such as blue mood, despair, anxiety, depression?	5	4	3	2	1

Do you have any comments about the assessment?

_____

_____

General health & Diabetes awareness questionnaire (Appendix – 7)

INDIAN DIABETES PREVENTION PROGRAMME-3
(UKIERI-IDRF)
India Diabetes Research Foundation & Dr. A. Ramachandran's Diabetes Hospitals
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Assessment of Awareness of General Health / Diabetes Assessment

Sl. No. : Place : Date :

Section A: Demographic profile:

1.	Name	:	
2.	Address with Telephone No: if available	:	
3.	Age	:	
4.	Sex	:	Male / Female
5.	Education	:	
6.	Occupation	:	
7.	Marital Status	:	Married / Unmarried
8.	Annual Income	:	
9.	Family History of Diabetes / CVD / Hypertension	:	
10.	Do you have any of these disorders	:	CVD / Hypertension

Section B: General Health

1. What types of activity do you consider to be physical activity?

Walking		Cycling	
Household chores		Climbing stairs	
Jogging/Running		Manual labour	
Indoor games		Gym Exercise	
Yoga		Others-(Pl .specify)	
		Don't know	

2. How much physical activity per day is healthy for a person?

Less than half an hour per day		More than one hour	
Half an hour to one hour		Don't know	

3. What do you consider to be a healthy and unhealthy diet?

Diet	Healthy	Unhealthy
Lot of vegetables		
Milk		
Mutton		
Pulses/sprouts		
Fats/Oils/Fried foods		
Soft drinks		
Bakery products		
Small feeds		
Spicy snacks		
Whole cereals		
Wheat/Ragi		
Fish		
Timely meals		
Root vegetables		
Sweets & Sugar		

4. Which of the following helps you to be healthy?

Periodical medical checkup		Timely intake of food	
Fat/Oil free foods		Regular exercise	
Taking limited sweets/sugar		Taking fruits/Salads	
Avoiding snacks/junk foods		Doing Yoga/Meditation	
Adequate sleep		Others (Specify)	
		Don't know	

5.What sources of information are most important for learning about health?

Doctors/Health staff		TV	
News paper/Print media-Posters/Stickers/Hand bills		Radio	
Hoardings		Friends	
Relatives/Family Members		Others (Specify)	
		Don't know	

Section-C : Diabetes awareness

1. What are the signs & symptoms of diabetes?

Frequent urination		Excessive thirst	
Loss of weight		Delayed healing of wounds	
Giddiness		Tiredness	
Excessive hunger		Others (Specify)	
		Don't know	

2.What are the causes of diabetes?

Family history of diabetes		Intake of excessive sweets/ sugar	
Overweight		Physical inactivity/lack of exercise	
High fat diet		Diabetes during pregnancy	
Stress/ Tension		Others (specify)	
		Don't know	

3. How does diabetes affect in the long run?

Heart problems		Foot problems/ Nerves	
Problems related to eyes		Any other problems	
Kidney problems		Don't know	

4. Will all people with diabetes get complications?

Yes	No	Don't Know

5. Do you think that it is possible to prevent diabetes?

Yes	No	Don't Know

If Yes, how?

Control of diet- Moderate intake of fats/Oils/sweets in food	
Regular exercise- Walking, Climbing stairs	
Yoga/ Meditation	
Weight reduction if over weight	
Others (specify)	

Effectiveness of mobile phone messaging in prevention of type 2 diabetes by lifestyle modification in men in India: a prospective, parallel-group, randomised controlled trial

Ambady Ramachandran, Chamukuttan Snehalatha, Jagannathan Ram, Sundaram Selvam, Mary Simon, Arun Nanditha, Ananth Samith Shetty, Ian F Godsland, Nish Chaturvedi, Azeem Majeed, Nick Oliver, Christofer Toumazou, K George Alberti, Desmond G Johnston

Summary

Background Type 2 diabetes can often be prevented by lifestyle modification; however, successful lifestyle intervention programmes are labour intensive. Mobile phone messaging is an inexpensive alternative way to deliver educational and motivational advice about lifestyle modification. We aimed to assess whether mobile phone messaging that encouraged lifestyle change could reduce incident type 2 diabetes in Indian Asian men with impaired glucose tolerance.

Methods We did a prospective, parallel-group, randomised controlled trial between Aug 10, 2009, and Nov 30, 2012, at ten sites in southeast India. Working Indian men (aged 35–55 years) with impaired glucose tolerance were randomly assigned (1:1) with a computer-generated randomisation sequence to a mobile phone messaging intervention or standard care (control group). Participants in the intervention group received frequent mobile phone messages compared with controls who received standard lifestyle modification advice at baseline only. Field staff and participants were, by necessity, not masked to study group assignment, but allocation was concealed from laboratory personnel as well as principal and co-investigators. The primary outcome was incidence of type 2 diabetes, analysed by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00819455.

Results We assessed 8741 participants for eligibility. 537 patients were randomly assigned to either the mobile phone messaging intervention (n=271) or standard care (n=266). The cumulative incidence of type 2 diabetes was lower in those who received mobile phone messages than in controls: 50 (18%) participants in the intervention group developed type 2 diabetes compared with 73 (27%) in the control group (hazard ratio 0·64, 95% CI 0·45–0·92; p=0·015). The number needed to treat to prevent one case of type 2 diabetes was 11 (95% CI 6–55). One patient in the control group died suddenly at the end of the first year. We recorded no other serious adverse events.

Interpretation Mobile phone messaging is an effective and acceptable method to deliver advice and support towards lifestyle modification to prevent type 2 diabetes in men at high risk.

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See Online for a podcast interview with Ambady Ramachandran

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Introduction

Primary prevention of type 2 diabetes is needed to reduce its increasing prevalence globally, particularly in low-income and middle-income countries.[1] Several randomised controlled trials have shown that lifestyle modification can reduce conversion from prediabetes to type 2 diabetes by 50%.[2–7] However, such programmes are labour intensive and have not been widely implemented, even in high-income countries. Mobile phone messaging (text messaging or short message service [SMS]) is an alternative method for delivery of educational advice and motivation to achieve lifestyle modification.[8–12]

Much work has been done to assess the use of mobile technology in disease management.[13] If successful, this method could be scalable, because mobile phones—with the low cost of SMS and their instant transmission—are used worldwide by people of all socioeconomic statuses.[13,14] Although the number of mobile phone messages sent globally tripled between 2007, and 2010,[15] robust data to support a successful role of mobile phone messaging in disease management are scarce. A Cochrane review[13] included only four randomised trials of 182 participants to provide a scientific evidence base for mobile phone messaging in management of all long-term disorders, and none of the studies assessed prevention of type 2 diabetes. Other reviews[8,16] have emphasised the paucity of randomised trials, although some data for disease management is emerging[10,17,18] and a role for mobile phone messaging in improvement of adherence to antiretroviral therapy has been established for people with HIV infection.[19] Despite the restricted evidence for mobile phone messaging in disease prevention,[14] the method is effective as part of an intervention for smoking cessation.[20]

India has a high prevalence of type 2 diabetes and widespread mobile phone ownership. We assessed whether tailored mobile phone messaging encouraging lifestyle change could reduce incident type 2 diabetes compared with standard lifestyle advice in Indian men with impaired glucose tolerance.

Methods

Study design and participants

We did this prospective, parallel-group, randomised controlled trial at ten sites in southeast India between Aug 10, 2009, and Nov 30, 2012. Working Indian men were screened for eligibility by questionnaire. The men were employed in public-sector and private-sector industrial units in southeast India (Chennai, Tamil Nadu and Visakhapatnam, Andhra Pradesh). The study was done in the workplace and because 96% of the employees were men, we included only men in the trial. Participants' jobs were self-classed as unskilled, skilled, or clerical or executive. Eligibility criteria were no diabetes (self-reported) or major illness, such as cancer, chronic liver or kidney disease; no disorders with cognitive impairment, severe depression or mental imbalance; no physical disability that would prevent regular physical activity; no recruitment in another trial; age 35–55 years; ownership of a mobile phone and ability to read and understand mobile phone messages in English; a positive family history of type 2 diabetes; and a BMI of 23 kg/m² or more. The study protocol was approved by the Ethics Review Committee of the India Diabetes Research Foundation. An independent safety committee assessed study progress with unmasked data at 6-monthly intervals. All patients gave written informed consent. Participants' physicians were informed of their participation in the trial.

***Panel 1*: Standard lifestyle advice and assessment of adherence**

Dietary recommendations

We individualised the dietary recommendations to balance food intake and physical activity and to maintain appropriate bodyweight. The advice included:

- Avoidance of simple sugars and refined carbohydrates
- Reduce total fat intake (<20 g per day)
- Restrict use of saturated fat
- Include more fibre-rich food—eg, whole grains, legumes, vegetables, and fruits

Dietary adherence

- Poor: not following the advice for more than 5 days a week (non-adherent)
- Fair: occasional deviation, following advice for 2–4 days a week (adherent)
- Good: strictly following diet advice for more than 5 days a week (adherent)

Physical activity recommendation

- To enhance aerobic exercise like walking, cycling, and jogging in sedentary patients
- Brisk walk for a minimum of 30 min per day (or equivalent), as a realistic goal with proven effectiveness
- Walk 3–4 km in 30 min at least 5 days a week
- Cycle 6–7 km in 30 min
- If occupation involves strenuous work, no specific advice

Physical activity adherence

- Poor: less than 150 min per week (non-adherent)
- Fair: 150–250 min per week (adherent)
- Good: more than 250 min per week or if occupation involved strenuous work (adherent)

Randomisation and masking

A central investigator not involved in analysis of trial data used a computer-generated randomisation sequence (Matlab randperm version 6) based on Marsaglia's algorithm[21] to randomly allocate patients (1:1) to individually tailored mobile phone messaging or to a control group that received standard lifestyle modification advice at baseline only.

Laboratory personnel and principal and co-investigators were masked to the participants' group allocation until the end of the study. Field staff and participants were, by necessity, not masked.

Procedures

After screening for eligibility, capillary blood glucose was measured with a glucometer (Accu-Check Sensor, Roche Diagnostics, Mannheim, Germany) at the participants' workplace 2 h after consuming 75 g oral glucose. Amongst the patients identified with impaired glucose tolerance, we invited those with 2 h blood glucose values of 8·9 mmol/L or more for a confirmatory oral glucose tolerance test within 1 week. During the second test, we collected venous blood samples at 0, 30, and 120 min.

At baseline, all participants received personalised education and motivation about healthy lifestyle principles, and written information about diet and physical activity. The prescribed lifestyle changes were similar to those used in a previous trial in India.[3] Participants were advised to balance food intake and physical activity and to achieve and maintain an appropriate bodyweight (panel 1). For physical activity, we asked participants with strenuous occupations and those who either walked or cycled for more than 30 min per day, or who already exercised regularly in other ways, to continue these activities (panel 1). We advised individuals who were sedentary or did light physical activity, as assessed in the initial interview, to walk briskly every day for a minimum of 30 min (panel 1).

After prescribing lifestyle changes, we reassessed all participants clinically and biochemically every 6 months from baseline. No additional lifestyle information or advice was routinely given by personal contact after the baseline visit in either the control or the intervention groups, except in response to specific queries from participants. In addition to standard lifestyle modification advice, participants in the intervention group received mobile phone messages at frequent intervals. These messages contained information about healthy lifestyle, the benefits of physical activity and diet, cues to start physical activity and healthy dietary practices, and

strategies to avoid relapse and remain motivated to maintain physical activity and healthy dietary habits.

The mobile phone message content at any time was based on the transtheoretical model of behavioural change.[22,23] This model is a stage-based concept of behavioural change, with individuals moving between discrete, qualitatively different stages of perception and action in relation to behavioural change. The model identifies five stages in the process of adoption of change: pre-contemplation, contemplation, preparation, action, and maintenance. In both groups, the transtheoretical model stage of each participant was assessed by questionnaire at baseline and review visits and the mobile phone message content in the intervention group was tailored according to their model stage.

A mobile phone messaging delivery manager website based on the transtheoretical model stage was created in partnership with Intel (Bangalore, India). The messages were delivered by a commercial service provider (Unicel technologies, India). They contained fewer than 160 characters and 60–80 messages were created for each transtheoretical model stage and sent cyclically, such that participants would not be likely to receive the same message in a 6-month period (on the basis of them receiving two to four messages per week). The assumption was that the participants would move from a pre-action stage to an action stage. The timing (0500–0800 h or 1700–2000 h) and frequency of mobile phone messaging were tailored to the participants' preferences, which were assessed at the 6-monthly visits. Panels 2 and 3 show sample messages. Participants were informed of the mechanisms for delivery of mobile phone messages and were expecting them in the agreed format.

The primary outcome was incident type 2 diabetes. Secondary outcomes were BMI, waist circumference, systolic and diastolic blood pressure, lipid profile (total and HDL cholesterol and triglycerides), total dietary energy intake, and physical activity score. The acceptability of mobile phone messaging was assessed by questionnaire in the intervention group. Ancillary analysis variables were not prespecified and included HOMA-IR and insulinogenic index calculated at baseline, and estimates of adherence to dietary and physical activity recommendations.

Oral glucose tolerance tests were done at baseline, 12 months, and 24 months, and were assessed by WHO recommendations.[24] Plasma was separated within 1 h for biochemical analysis. The samples were kept at –20°C for insulin assay. To minimise discomfort and inconvenience, at 6 months and 18 months a capillary blood sample was taken 2 h after oral glucose was given in the fasting state. If this value was 11·1 mmol/L or greater, a 2 h oral glucose tolerance test was done within 1 week with venous plasma sampling in the fasting state, and at 30 min and 2 h after glucose consumption. Type 2 diabetes was defined by a fasting plasma glucose concentration of 7·0 mmol/L or more or a concentration from the 2 h oral glucose tolerance test of 11·1 mmol/L or more, or both.[24] Participants diagnosed with type 2

Panel 2: Examples of mobile phone message reminders for physical activity, tailored according to stage of transtheoretical model

Pre-contemplation
- "Physical activity helps to maintain normal blood sugar and blood pressure."
- "Active life makes you live longer."

Contemplation
- "Moderate physical activity keeps you healthy."
- "Desk-bound job? Take short walk to relax your body and mind."

Preparation
- "Use stairs instead of a lift."
- "Get off the bus one or two stops ahead and walk to the destination."

Action
- "All you need is 30 minutes of moderate physical activity on most days of the week."
- "A good exercise can keep your mind stress free."

Maintenance
- "Were there many missed walks this month? No worries start today."
- "Are you stressed out! Stress increases blood sugar. Go for a walk and relax."

Panel 3: Examples of intervention-group mobile phone message reminders for diet, tailored according to stage of transtheoretical model

Pre-contemplation
- "Eat healthy, be healthy and be happy."
- "Regular eating pattern helps to maintain normal blood sugar."

Contemplation
- "Avoid snacks while watching TV, you may overeat."
- "Neither fast nor feast, have a balanced diet"

Preparation
- "Increase fibre rich foods, fruits and vegetables and whole cereals."
- "Make your plate colourful by adding lots of vegetables."

Action
- "Take fruits as a whole and not as a juice."
- "Fruits are delicious and nutritious, include them as part of your diet."

Maintenance
- "Skipping breakfast will make you overeat at lunch."
- "Hope you had a healthy week!"

diabetes were referred to their physicians for further management.

We measured height at baseline. Weight (BMI), waist circumference, and blood pressure (mean of two readings) by sphygmomanometer were measured at each visit by standard procedures. Plasma glucose (hexokinase method, coefficient of variation <3% at 10·0 mmol/L and 20·0 mmol/L) was measured at each visit. Fasting triglycerides, total cholesterol and HDL cholesterol were measured annually with an auto analyser with appropriate quality control. Plasma insulin was measured at baseline in the fasting state, at 30 min, and 2 h after oral glucose consumption by chemiluminescence (ELICA, Roche diagnostics). We calculated insulin resistance at baseline and at year 2 with the international HOmeostasis Model Assessment of Insulin Resistance (HOMA-IR) formula ([fasting insulin (mU/l)xfasting glucose (mmol/l)]/22·5).[25] We calculated the insulinogenic index at baseline and at year 2 by dividing the increment in insulin at 30 min by glucose at 30 min during the oral glucose tolerance test.[26]

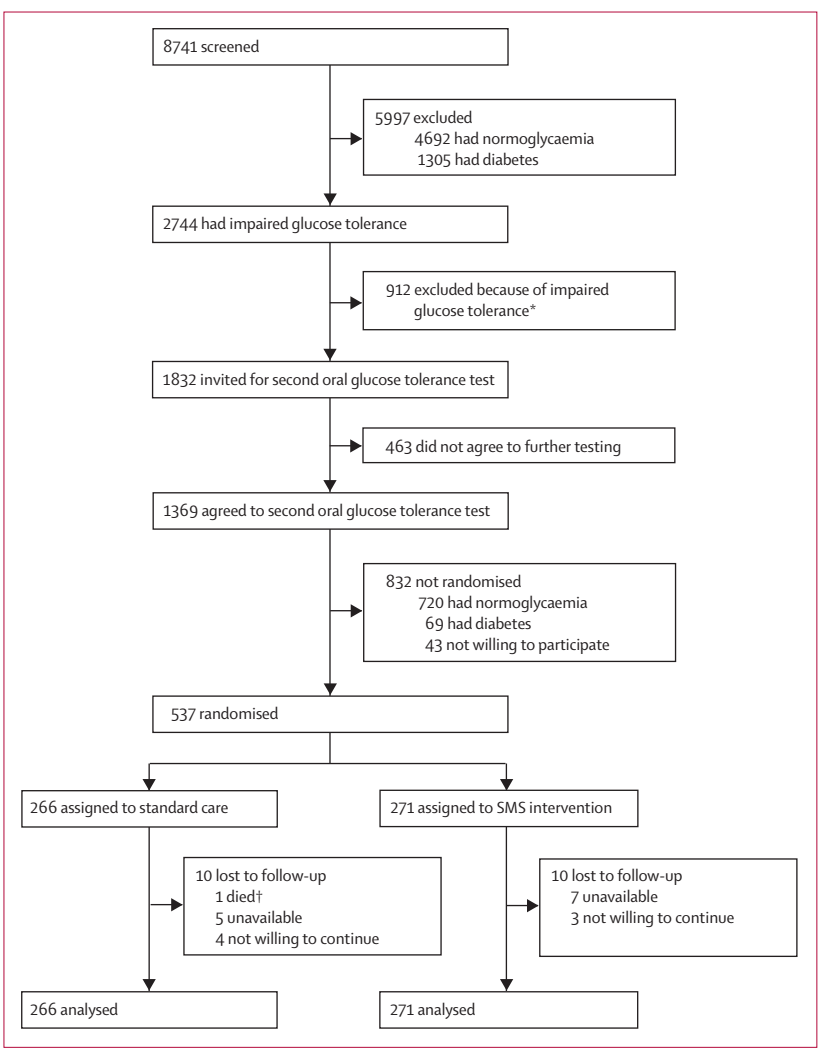

Figure 1: **Trial profile**
*2 h glucose <8·9 mmol/L. †Cardiac arrest.

Physical activity and dietary intake were assessed by questionnaire completed with fieldworkers at baseline and during the 6-monthly reviews. Physical activity was quantified on a score of 7–70.[3] The activity questionnaire was based on that used previously in south-Asian Indians in an epidemiological UK survey, which we used in our previous study of diabetes prevention in India,[3,27] but was slightly modified for the Indian environment. At each visit we assessed dietary intake by 24 h recall. Information about adherence to recommendations for dietary intake and physical activity was recorded at the 6-monthly reviews. Adherence was self-reported, on the basis of weekly patterns, and was scored as poor, moderate, or good (panel 1).[3] For statistical analysis, we categorised data as adherent or non-adherent. We calculated energy intake for individual food items with the National Institute of Nutrition guidelines for India.[28]

We assessed acceptability of mobile phone messages in the intervention group with a short questionnaire developed specifically for this trial. Scoring (0 or 1) was based on responses to questions about message content and frequency, ease of understanding, whether the messages were considered a disturbance, and whether it was perceived as helpful in improvement of lifestyle. A total score of 6 was the most acceptable and 0 the least. The questionnaire also queried the preferred time of day to receive mobile phone messages and invited suggestions for improvements. Assessments were done by seven field staff trained in undertaking glucose tolerance tests and biometric measurements. Training was done by central training staff with use of continuous training methods previously used in our diabetes projects in India.[3] Each person had a designated role to minimise inter-individual error.

Statistical analysis

With the assumption of a 30% cumulative incidence of type 2 diabetes over 2 years (in our previous study in India, which had similar eligibility criteria,[3] the incidence was 55% over 3 years), at 5% significance with 80% power, 214 participants per group were needed for a 40% reduction in progression to type 2 diabetes to be detected. In a meta-analysis of behavioural modification studies[7] the mean reduction was 50% and we assumed that mobile phone messaging would be less effective than personal contact. We aimed to recruit 514 participants (257 in each group) to allow for 20% dropout rate during follow-up.

We did analysis by intention to treat. We calculated the estimated cumulative incidence of type 2 diabetes using unadjusted Cox regression analysis to compute the hazard ratio (HR) and survival curve for the intervention versus the control groups. The number needed to treat and 95% CI to prevent one case of type 2 diabetes as the inverse of the absolute risk reduction (RR) and its 95% CI. To assess the effects of the intervention on

secondary outcomes (and ancillary analysis variables) we used mixed-linear regression modelling with maximum likelihood parameter estimation for continuous variables. We log-transformed skewed variables (triglycerides and physical activity score) before analysis. Differences in the estimated marginal means between the groups with 95% CIs are shown. We analysed categorical outcomes (adherence to diet and physical activity) with a generalised estimating equation-based logistic regression analysis, with adjustment for baseline values and time. The corresponding odds ratios (and associated 95% CIs) with p values are shown.

We computed changes by subtraction of final follow-up values from baseline values; for participants who developed type 2 diabetes, we regarded the values at the time of diagnosis as final. We used Cox regression analysis to assess the effect of change in secondary outcome, and ancillary analysis variables; baseline values of 2 h glucose; HOMA-IR; and insulinogenic index on incident type 2 diabetes. We did statistical analyses with SPSS (version 19.0).

This study is registered with ClinicalTrials.gov, number NCT00819455.

Role of the funding source

The evaluation board of the UK–India Education and Research Initiative (UKIERI) assessed the outline protocol in a competitive funding process, but neither UKIERI nor the World Diabetes Foundation had a role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication.

Results

Figure 1 shows the trial profile. Of 2744 eligible participants, 1369 (50%) agreed to a second oral glucose tolerance test. Of these, 580 (42%) had persistent impaired glucose tolerance, of whom 43 (7%) did not wish to participate further. 537 participants were randomly assigned to the mobile phone messaging intervention (n=271) or to standard care (n=266), and were included in the primary analysis. Baseline characteristics were similar between groups (table 1). Most workers were in a skilled or clerical or executive role (table 1). At entry, no participant in either group was receiving lipid modifying treatment, but 69 (26%) in the intervention group and 69 (25%) in the standard care group were taking hypotensive drugs. Dietary energy intake, compatibility of diet with advice during the trial, and the distribution of physical activity scores were similar in both groups at baseline (table 1). At final follow-up, the response rate was 96% (n=517; figure 1).The mean duration of follow-up was 20·2 months (SD 7·0).

Three patients (two [<1%] in the control group and one [<1%] in the intervention group) were diagnosed with type 2 diabetes by treating physicians outside the trial. These patients were included in analysis after the diagnosis was confirmed from medical records. Other cases were ascertained during the trial. Including the three patients who had already been diagnosed, 50 (18%) men in the intervention group developed type 2 diabetes over the 2 years compared with 73 (27%) control patients (absolute risk reduction 9%; figure 2).The intervention reduced the incidence of type 2 diabetes during the course of the study (β –0·447; figure 2). The number needed to treat to prevent one case of type 2 diabetes was 11 (95% CI 6–55).

Repeated measures ANOVA showed no significant effect of the intervention on BMI, waist circumference, blood pressure, or serum cholesterol and triglycerides, but the effect on HDL cholesterol was significant (table 2). Total dietary energy intake was lower in the intervention group than in the control group, whereas physical activity scores did not differ (table 2).At the end of follow-up, a greater proportion of participants in the intervention group were adherent to diet than in the standard-care group (table 2), but adherence to physical activity recommendations did not differ between the two groups (table 2). Significant predictors of incident type 2 diabetes were high BMI, low dietary compliance, high baseline HOMA-IR and 2 h plasma glucose, and reduced baseline insulinogenic index

	Control group (n=266)	Intervention group (n=271)
Age (years)	46·1 (4·6)	45·9 (4·8)
Occupation		
Unskilled	11 (4%)	9 (3%)
Skilled	170 (64%)	164 (61%)
Clerical or executive	85 (32%)	98 (36%)
Family history of diabetes	131 (49%)	150 (55%)
BMI (kg/m²)	25·8 (3·0)	25·8 (3·3)
Waist circumference (cm)	92·7 (7·3)	92·6 (7·1)
Blood pressure (mmHg)		
Systolic	123·4 (14·3)	123·1 (13·6)
Diastolic	80·2 (8·4)	80·2 (8·4)
Receiving hypotensive drugs	69 (26%)	69 (25%)
Plasma glucose (mmol/L)		
Fasting	5·70 (0·55)	5·63 (0·53)
2 h	8·90 (0·86)	8·79 (0·78)
Serum lipids (mmol/L)		
Total cholesterol	4·91 (0·94)	4·87 (0·89)
HDL cholesterol	0·90 (0·19)	0·90 (0·21)
Triglycerides	1·6 (1·2–2·3)	1·6 (1·1–2·1)
HOMA-IR*	3·2 (1·5)	3·0 (1·3)
Insulinogenic index (pmol/mmol)	48·9 (27·9–78·5)	47·6 (30·0–81·7)
Dietary energy intake (kcal/24 h)	2100·0 (278·0)	2121·0 (296·0)
Baseline diet compatible with advice during trial	136 (51%)	141 (52%)
Physical activity score	36 (31–56)	36 (27–54)

Data are mean (SD), n (%), or median (IQR), unless otherwise indicated. HOMA-IR=HOmeostasis Model Assessment of Insulin Resistance. *Dimensionless measure.

Table 1: **Baseline characteristics**

(table 3). Significance of each variable was sustained on entry into a Cox proportional hazard model (data not shown). Randomisation group was not included in this model due to co-linearity with dietary compliance.

The frequency of mobile phone messaging at baseline was decided individually in line with participants' wishes and initially a median of 18 messages per month (range 8–24) were requested. At final follow-up, the median requested was 12 (range 8–16). Analysis of the acceptability questionnaire data showed that messages were generally welcomed, and the median questionnaire score out of 6 was 5 (range 3–6). No more than eight (3%) of 271 people at any review stated that receiving the messages was disturbing them.

One patient in the control group died suddenly at the end of the first year. We recorded no other serious adverse events.

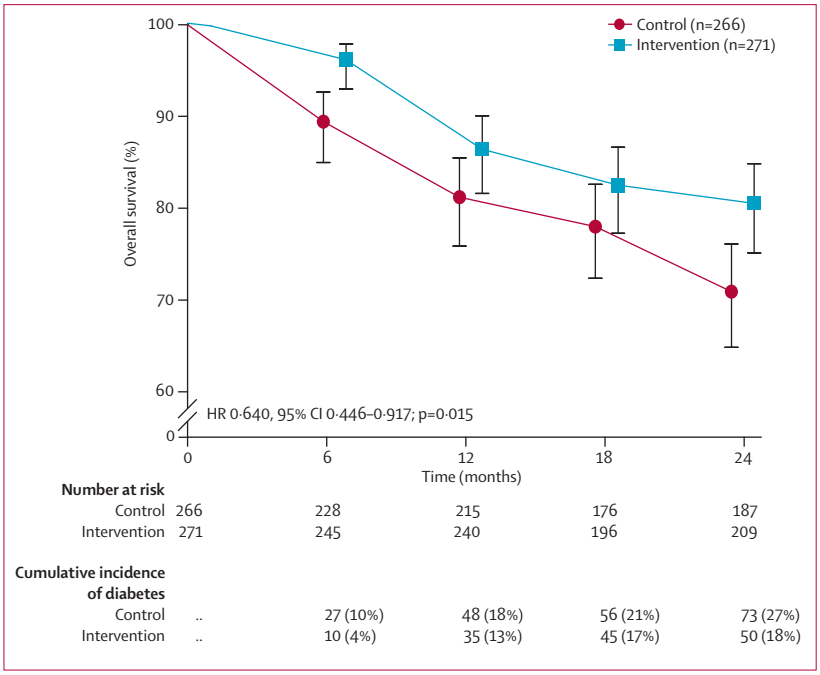

***Figure 2*: Probability of remaining free of type 2 diabetes**
Data are n (%), unless otherwise indicated. Error bars show 95% CIs. Eligibility assessed according to WHO criteria. HR=hazard ratio.

Discussion

Our findings show that mobile phone messaging can be an effective technique for lifestyle modification to reduce incidence of type 2 diabetes. The mobile phone messages were generally well accepted (panel 4).

Participants in this trial were at particularly high risk for development of type 2 diabetes on the basis of 2 h glucose concentrations at first oral glucose tolerance test. The cumulative incidence of type 2 diabetes was lower in those who received the mobile phone messaging intervention than in controls. We noted the glycaemic benefits from mobile phone messaging early in the study (at 6 months), showing that their effect was rapid. The reduction in progression to type 2 diabetes was similar in magnitude to that reported in our previous study of diabetes prevention in India in which personal contact methods were used.[3]

We aimed to induce dietary change and increase physical activity. Mobile phone messaging was associated with reduced dietary energy intake on recall; however, reported physical activity and bodyweight were similar in the intervention and control groups. This apparent

	Control group (n=266)	Intervention group (n=271)	Difference in mean change (95% CI)
Anthropometry			
BMI (kg/m²)	25·0 (5·4)	25·0 (5·5)	−0·05 (−0·46 to 0·37)
Waist circumference (cm)	92·6 (7·7)	92·6 (7·9)	0·04 (−0·56 to 0·64)
Blood pressure (mm Hg)			
Systolic	121·4 (13·0)	121·4 (13·0)	0·04 (−0·96 to 1·03)
Diastolic	78·8 (7·4)	78·7 (7·3)	−0·07 (−0·64 to 0·49)
Serum lipids (mmol/l)			
Total cholesterol	4·9 (0·9)	4·9 (0·9)	0·010 (−0·08 to 0·10)
HDL cholesterol	0·9 (0·2)	1·0 (0·2)	0·033 (0·011 to 0·054)
Triglycerides*	1·60 (1·22–2·27)	1·52 (1·16–2·09)	−0·080 (−0·17 to −0·06)
Dietary energy intake (kcal)	2042·5 (269·8)	1998·7 (295·4)	−43·7 (−65·5 to −22·0)
Physical activity score*	38·0 (25·0–54·0)	39·0 (27·0–54·0)	−1·0 (−2·0 to 0)
Difference in percentage adherence (OR [95% CI]; p value)†			
Diet	..	1·357 (1·008–1·826; p=0·0442)	..
Physical activity	..	1·110 (0·779–1·573; p=0·572)	..

Data are mean (SD) or median (IQR), unless otherwise indicated. We used mixed-linear regression analysis, taking into account visit and intervention, to generate estimated marginal means and difference in mean change (95% CI) at the end of follow-up. *Log-transformed data (by back transformation). †Logistic regression analysis with repeated measures taking into account visit and intervention to compare adherence to diet and physical activity between groups.

***Table 2*: Secondary outcomes and adherence to dietary intake and physical activity recommendations at the end of follow-up**

	HR (95%CI)	p value
2 h glucose*† (mmol/L)	1·728 (1·406–2·122)	<0·0001
HOMA-IR‡	1·175 (1·075–1·285)	<0·0001
Insulinogenic index† (pmol/mmol)	0·993 (0·988–0·998)	0·006
Change in BMI (kg/m²)	1·329 (1·151–1·535)	<0·0001
Change in dietary adherence	0·482 (0·327–0·710)	<0·0001

We entered significant predictors of incident diabetes into a Cox proportional hazards model; randomisation group was not included as a variable because of co-linearity with change in dietary adherence. HOMA-IR=HOmeostasis Model Assessment of Insulin Resistance. BMI=body-mass index. *By oral glucose tolerance test. †At baseline. ‡Dimensionless measure.

***Table 3*: Independent, significant change in secondary outcome variables and baseline variable predictors of incident diabetes**

independence of glycaemic benefit from bodyweight reduction or increase in physical activity has been reported in some previous conventional diabetes prevention programmes.[2,3] In this study, we assessed physical activity by questionnaire only, a method that could have missed small changes. Although we have previously shown increased physical activity in lifestyle practice groups,[3] as with other studies,[4,5] the physiological basis for benefit is unclear. At follow-up, concentrations of HDL cholesterol were slightly, but significantly, higher in the control versus the intervention groups. Weight loss and increased physical activity are two determinants of circulating concentrations of HDL, but in our study we could not be sure of the mechanism behind this finding. Raised concentrations have been reported previously in similar studies of prediabetes interventions.[4,29]

Our results show that baseline 2 h concentrations of plasma glucose and HOMA-IR were predictive of incident type 2 diabetes, and increased β-cell function was protective. Irrespective of study group, increased BMI was associated with high incidence of type 2 diabetes, which is in line with previous findings.[4,5]

Our study has some limitations. First, we included only working men. Women's responses and reactions to mobile phone messages might differ from those of men, but we would have recruited insufficient women to assess the effects of sex. Therefore, investigators of future studies should assess the effectiveness and acceptability of SMS in women and in other groups of men. Second, the setting was in an urban population in India. The application of mobile phone messaging to other populations should be studied. Third, although our methodology attempted to minimise bias, the fieldworkers were, by necessity, not masked; thus, we cannot exclude the possibility of bias, however unlikely. We used the transtheoretical model as the basis for the lifestyle modification strategy. Although this model has a substantial evidence base,[22] it is not uniformly accepted[23] and we cannot be sure of its importance in this trial because other methods were not studied.

Because mobile phone messaging is potentially scalable and likely to be low cost, its use in large prevention programmes warrants assessment, especially because the benefits of prevention or delaying of onset of type 2 diabetes can persist for up to 20 years.[30–32] Furthermore, benefits extend to other cardiovascular risk factors and possibly to cardiovascular events.[27] Finding a way to implement behaviour modification programmes cost-effectively remains a medical challenge. Personal contact methods will probably remain expensive, and innovative solutions have been sought for primary care and workplace settings.[33] Mobile phone messaging could form part of an alternative strategy.

***Panel 4*: Research in context**

Systematic review

We searched PubMed, Cocharane reviews, and Google for systematic reviews and published original studies from 2002 onwards that were written in English. We used the search term "prevention and management of diabetes and other chronic diseases using mobile phones". Previous studies have shown that type 2 diabetes can be prevented or delayed by lifestyle modification programmes delivered by direct contact methods .[7] Furthermore, a previous systematic review[16] showed that mobile phone messages can help induce lifestyle change, including smoking cessation. Evidence from randomised trials of the effectiveness of mobile phone messaging in the management of chronic disease is scarce, as are findings for type 2 diabetes management or prevention.[8,13,16]

Interpretation

This trial is the first to show benefit from a targeted mobile phone messaging intervention as a technique in the prevention of type 2 diabetes. Our findings showed similar preventive effectiveness as that noted with direct contact methods.[3] Mobile phone messaging was acceptable to the recipients, is potentially scalable, could be delivered at low cost, and is now part of an alternative strategy.

Contributors

AR and DGJ were the principal investigators and designed and undertook the study and prepared the manuscript. CS supervised the study conduct, analysed the data, and prepared the manuscript. JR contributed to recruitment, data collection, and statistical analysis, and helped in manuscript writing. SS and MS contributed to recruitment and data collection. AN, ASS, IFG, NC, AM, NO, CT, and KGA helped in interpretation of the results and reviewed the manuscript.

Conflicts of interest

DGJ and NC are supported by the UK National Institute for Health Research (NIHR). Imperial College London is grateful for support from the NIHR Collaboration for Leadership in Applied Health Research and Care and the Imperial NIHR Biomedical Research Centre. We declare that we have no conflicts of interest.

Acknowledgments

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Plant, India) for allowing us to undertake this medical survey; Intel Health Systems Research Centre, Bangalore, for developing the software platform for sending the messages; and K Raghavan, N Murugesan, and P Rama Rao of the India Diabetes Research Foundation for serving as members of the safety committee of the trial.

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ORIGINAL ARTICLE

Screening among Male Industrial Workers in India Shows High Prevalence of Impaired Glucose Tolerance, Undetected Diabetes and Cardiovascular Risk Clustering

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Abstract

Objective: To study the magnitude of undetected diabetes, impaired glucose tolerance (IGT) and clustering of cardiometabolic risk factors among male industrial workers.

Methods*:* Measurements of 2h post glucose blood glucose (2h PG), blood pressure, body mass index (BMI) and waist circumference (WC) were done in 8741 non-diabetic men of 35-55 years. Presence of family history of diabetes (FH) was noted. Risk associations with diabetes and IGT were studied using multiple logistic regression analysis. Clustering of overweight/obesity, abdominal obesity, hypertension was noted.

Results: Prevalence of undetected diabetes (14.9%) and IGT (31.4%) were high. FH, age, hypertension and BMI showed strong associations with diabetes and IGT. More than 40% had clustering of risk factors.

Conclusion: High prevalence of undetected diabetes, IGT and clustering of cardiometabolic risk factors among young industrial workers mandates that regular screening for metabolic disorders should be undertaken to prevent development of severe morbidity in the productive years of life.

Introduction

The escalating prevalence of type 2 diabetes mellitus (T2DM) poses a worldwide public health crisis. The challenge is immense in developing countries like India, which are undergoing rapid socio-economic transition.[1] Economic growth and transition to modern lifestyle among the Indian population which have occurred in the last four decades have resulted in a steady increase in the prevalence of T2DM.[2-5] The prevalence of Impaired Glucose Tolerance (IGT) is high[1] suggesting the presence of a large pool of people with the potential to develop T2DM. As IGT is also associated with cardiovascular risk factors, its identification is of paramount importance for prevention and control of T2DM and cardiovascular diseases (CVD). Simple screening procedures among non-diabetic persons can detect undiagnosed diabetes, IGT and also the presence of multiple risk factors for diabetes and CVD.

In this study, in a large group of male industrial workers, association of the potential modifiable risk factors (body mass index (BMI), waist circumference (WC) and hypertension) for dysglycaemia were assessed. The prevalence of cardiovascular risk clustering and its association with dysglycaemia were also studied. The screening was done for selecting IGT subjects for a prospective diabetes prevention study.

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Table 1 : Results of screening oral glucose tolerance test (OGTT) (only men)

Characteristics	Total	NGT	IGT	Diabetes
N	8741	4692 (53.7)	2744 (31.4)	1305 (14.9)
	n (%)	n (%)	n (%)	n (%)
Occupation (n=8148)				
Unskilled	318 (3.9)	202 (4.6)	79 (3.1)	37 (3.0)
Skilled	6297 (77.3)	3291 (75.4)	1986 (78.0)	1020 (82.5)
Executive /Clerical/ Professional	1533 (18.8)	872 (20.0)	482 (18.9)	179 (14.5)
Family history (n=8679)	2768 (32.0)	1351 (29.2) (n = 4633)	939 (34.6) (n=2715)	478 (37.0)* (n=1293)
Overweight (BMI 23.0 – 24.5 kg/m^2)	2097 (24.0)	1178 (25.1)	641 (23.4)	278 (21.3)#
Obese (BMI ≥ 25.0 kg/m^2)	4865 (55.7)	2403 (51.2)	1632 (59.5)	830 (63.6)*
Abdominal Obesity (WC ≥ 90 cm) (n=6854)	4003 (58.4)	1870 (53.8) (n=3476)	1444 (61.6) (n=2345)	689 (66.7)* (n=1033)
Hypertension (n=8679)	4819 (55.5)	2353 (50.4) (n=4668)	1593 (58.5) (n=2722)	873 (67.7)* (n=1289)
		Mean ± SD		
Age (Years)	45.7 ± 5.0	45.4 ± 5.1	45.8 ± 4.6	46.8 ± 4.9**
Body mass index (kg/m^2)	25.5 ± 3.4	25.2 ± 3.3	25.8 ± 3.3	26.3 ± 3.5**
Waist circumference (cm)	91.1 ± 8.0	90.1 ± 7.8	91.7 ± 7.9	93.1 ± 8.3**
Blood Pressure (mmHg)				
Systolic	126.7 ± 16.2	125.2 ± 15.5	127.2 ± 16.4	130.8 ± 17.3**
Diastolic	84.1 ± 10.9	82.9 ± 10.7	85.1 ± 10.6	87.1 ±11.3**

Trend Chi-Square- * p < 0.0001, # p = 0.011, One Way ANOVA - ** -p < 0.0001

Material and Methods

Sample selection

Study subjects were recruited from middle-class populations working in various public and private sector industrial units in Chennai, Tamil Nadu and Visakhapatnam, Andhra Pradesh, India. Following agreement from the selected employers and written consent from the employees, details of the programme were explained and all the staff were screened.

Non-diabetic subjects with no major illness, aged 35-55 years, were screened from August 2009 to November 2010. The study protocol was approved by the Institutional Ethical Review Committee of the India Diabetes Research Foundation (IDRF).

Among the 9160 non-diabetic subjects (men: women 8801:359) invited, 9079 (men: women 8741:338) subjects consented to undergo the screening test. As the number of women was small, the analysis was done only for men (n=8741, response rate 99.3%). Weight and height were measured with the participants wearing light clothes without shoes. BMI was calculated (kg/m^2). Waist circumference was measured midway between the lower rib margin and iliac crest. Blood pressure was measured using a standard mercury sphygmomanometer after a 5-minute rest. An average of the two readings was used for the analysis. Demography, family history of diabetes, heart disease, and stroke were recorded in a structured questionnaire. Screening was carried out at the work place. Capillary blood glucose was measured using a glucometer (Accu–check Sensor, Roche Diagnostics, Mannheim, Germany), 2h after glucose intake (75 gms). The participants were advised not to do any strenuous work during the screening period.

Definition of variables and outcomes

Glucose tolerance was classified according to the 1999 World Health Organisation (WHO) criteria.[6] T2DM was defined as 2 hr OGTT plasma glucose levels ≥ 200 mg/dl (≥ 11.1 mmol/l) and IGT as a plasma glucose concentration of 140 to 199 mg/dl (7.8 to 11.0 mmol/l). BMI between ≥ 23.0 and 24.9 kg/m^2 was considered as overweight, and BMI ≥ 25.0 kg/m^2 was defined as obese. Central obesity was indicated by waist circumference of ≥ 90 cm. Subjects with a history of hypertension and newly diagnosed cases with blood pressure readings ≥ 130/85 mmHg were categorised as hypertensive.

For this study, only persons with IGT were selected. Presence of impaired fasting glucose (IFG) was not a selection criterion. However, a few of the IGT subjects could also have had IFG.

Data Analysis

Statistical analyses were carried out using SPSS 19.0 statistical software system (IBM statistics). Continuous variables were expressed as mean ± SD and evaluated using one way analysis of variance (ANOVA) with Bonferroni correction post hoc. The χ^2 statistic test was applied for categorical variables. Multiple logistic regression analysis with forward stepwise addition was used to determine the

Table 2 : Results of multiple logistic regression analyses, variables significantly associated with impaired glucose tolerance (IGT) (Panel-1) and Diabetes (Panel-2) are shown

Variables	β	SE β	p value	Odds Ratio (OR)	95% CI (OR)	
					Lower	Higher
Panel 1: Dependent variable : Impaired glucose tolerance Vs Normal glucose tolerance						
Diabetes Family history	0.335	0.059	0.000	1.398	1.247	1.56
Hypertension	0.261	0.055	0.000	1.298	1.165	1.44
Body Mass Index (kg/m^2)	0.055	0.008	0.000	1.056	1.039	1.07
Age (Years)	0.019	0.006	0.003	1.019	1.007	1.03
Panel 2: Dependent variable: Diabetes Vs Normal glucose tolerance						
Hypertension	0.57	0.074	0.000	1.768	1.529	2.04
Diabetes Family history	0.49	0.078	0.000	1.633	1.402	1.9
Age (Years)	0.059	0.008	0.000	1.061	1.043	1.07
Body Mass Index (kg/m^2)	0.038	0.017	0.028	1.039	1.004	1.07
Waist circumference (cm)	0.029	0.007	0.000	1.029	1.014	1.04

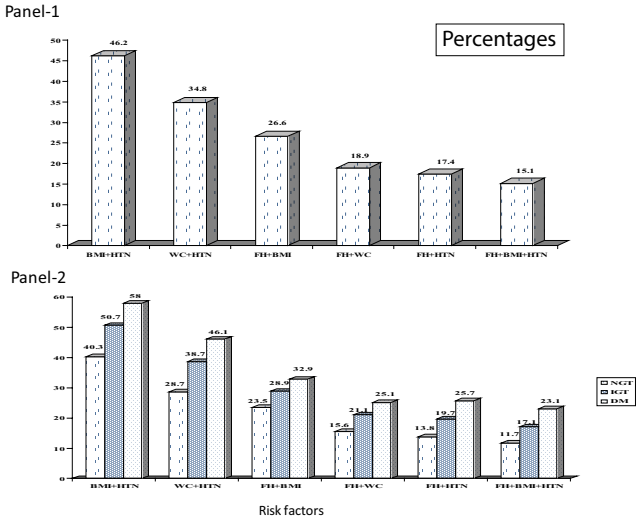

Fig. 1 : Panel-1 shows prevalence (in percentages) of the clusters of risk factors in the total group. Panel-2 shows the clusters of risk factors in categories of glucose tolerance. Prevalence of the clusters increased gradiently with increasing glucose intolerance. (IGT > NGT, DM > IGT(p < 0.0001 in all groups))

association of variables with glucose abnormalities. Regression analyses were done using newly diagnosed diabetes vs normoglycaemia (NGT), and IGT vs NGT as the dependent variables.

Results

During the screening, IGT was detected in 2744 (31.4%) participants. As IFG was not a selection criterion, we did not assess the prevalence of IFG + IGT among the study subjects. Newly diagnosed diabetic cases n=1305 (14.9%) were referred to the company physicians for appropriate treatment.

Table 1 shows the characteristics of the subjects who underwent the screening in relation to the glycaemic results. Mean age was 45.7 ± 5.0 years; positive family history was present in 32.0%. Diabetic subjects were older, had higher BMI, WC and blood pressure (p < 0.05) when compared with NGT and IGT subjects (p < 0.05). Positive family history of diabetes, and blood pressure showed progressive increase from NGT to DM (p < 0.0001 for all).

Significant risk associations for IGT and T2DM are shown in Table 2. Positive family history of diabetes, BMI, age and hypertension were associated with diabetes and IGT. WC also showed an association with diabetes.

Figure 1 shows the prevalence of risk clusters, in the prediabetic and diabetic subjects. Clustering of risk factors (2 or more) were present in many subjects, the most frequent cluster was overweight / obesity (BMI ≥ 23 kg/m^2) and hypertension (46.2%), followed by abdominal obesity + hypertension (34.8%) (Figure 1, Panel-1). Clustering of 3 risk factors occurred in 15.1% (Figure 1, Panel-1). As expected, prevalence of risk clusters increased with degree of hyperglycaemia, the percentages gradiently increased from NGT to diabetes. (IGT > NGT, DM > IGT(p < 0.0001 in all groups)) (Figure 1, Panel-2).

Discussion

The screening results showed that among Indian industrial workers aged 35-55 years, prevalence of undetected diabetes (14.9%) and IGT (31.4%) were high. We had chosen men working in varied industrial organisations, comprising of unskilled and skilled labourers, clerical and executive personnel.

Nearly 80% of the study participants were overweight or obese (24% overweight and 55.7% obese) and 58.4% had abdominal obesity. This proportion was higher when compared with data collected in 2006 in a similar city population in the same age group (total 71.5%: 28.5% overweight and 43% obese).[7] It is likely that the prevalence of obesity has increased in urban Indian men. It is also possible that, overweight persons would have volunteered for this programme, being aware of their high risk for diabetes and other lifestyle disease. A positive

family history of diabetes was present in 32.0% which was similar to the prevalence of 34.2% noted among the city population in our previous study.[7] In this study, 55.5% of the study subjects had hypertension (BP ≥ 130/85 mmHg). Hypertension was a strong risk factor both for IGT and diabetes. Risk associations of hypertension with IGT and diabetes were similar. BMI and WC were independently associated with diabetes.

A large study on men working in industrial setting (n=2122, mean age of 42 years), in New Delhi,[8] reported high prevalence of diabetes (15%), hypertension (30%, blood pressure >139/89 mmHg or on anti hypertensive treatment) and pre hypertension (44%). Prevalence of overweight (BMI ≥ 23 kg/m^2) was 58.5% and 43% had abdominal obesity (waist circumference ≥ 90 cm). Our study cohort had higher prevalence of overweight and abdominal obesity than in the above report. Prevalence of IGT was similar in both the studies. We had assessed the prevalence of only newly diagnosed diabetes, and it was as high as the total prevalence reported in the above study.[8] The total prevalence of known and new diabetic cases in Chennai would be higher. In a previous urban study, prevalence of known and newly diagnosed T2DM in men of 35-55 years was 24.5% and 8.6% respectively.[7] However, prevalence of IGT was only 11.0% in this group.

A higher percentage of hypertension (55.5%) seen in the present study could be partly due to the lower cut-off values of blood pressure used and partly due to the higher prevalence of hypertension associated with diabetes.

Although, not a community-based epidemiological survey, the study shows a high prevalence of undetected diabetes and IGT among male industrial workers in southern India. Screening with 2h blood glucose is a highly sensitive method to identify diabetes and IGT in Indians. However, a few cases of diabetes and IFG could be missed as fasting glucose is not measured. Multiple risk factors and their clusters were present in many of them. Several studies in India have shown that clustering of risk factors or metabolic syndrome is highly prevalent in the population.[9-11] The association of risk factors for IGT and diabetes were similar. These risk factors also contribute to the development of CVD.[12] Development of complications of diabetes can be reduced by early diagnosis and management of diabetes and also by appropriate intervention in the prediabetic stage itself. Periodic screening for dysglycaemia should be conducted among the industrial workers to reduce the burden of metabolic diseases.

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