



Original research

The impact of multiple lifestyle interventions on remission of type 2 diabetes mellitus within a clinical setting



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ABSTRACT

Aims: To assess the impact of multiple lifestyle interventions (LSI) in type 2 diabetes mellitus. (T2DM)
Methodology: T2DM subjects were enrolled in a one year LSI program consisting of diet, exercise, diabetes education and pharmacotherapy review with support from a diabetes educator (DE). Outcome measures were weight loss, medication and diabetes status.
Results: n = 45 Indian subjects with T2DM. Weight loss at the end of one year: > 10% n = 12 (26.8%); 5–10% n = 9 (20%); < 5% n = 20 (44.4%) (p < 0.05), weight gain (1–3 kg) n = 4 (8.8%). 41 participants gained 2.8 ± 0.9 kg in years 1–5. Remission of T2DM at one year n = 35 (77.8%) and at five years n = 21 (51.2%). Treatment cost savings at one year = \$189/patient/year and \$145/patient/year during years 1–5; an average saving of \$765/patient over 5 years.
Conclusion: Intensive LSI over one year resulted in weight loss, improved glycaemic control and T2DM remission in the majority of subjects. Medication costs were reduced. Over five subsequent years, diabetes remission persisted in the majority despite modest weight regain.

1. Introduction

Type 2 diabetes mellitus (T2DM) is a heterogeneous disorder accounting for 90–95% of cases of diabetes mellitus (DM) and is primarily characterized by a decline in β -cell function resulting in progressive decline of insulin secretion and worsening of insulin resistance (IR) (American Diabetes Association, 2015). T2DM is considered to be an incurable, chronic and progressive condition (Kaufman, 2005) with the rate of progression of disease governed by modifiable risk factors (obesity, sedentary lifestyle, diet and smoking) and non-modifiable risk factors (Family history, ethnicity, age) (Wu et al., 2014).

Obesity is a potent independent risk factor for the development and progression of T2DM determined by both the degree of obesity and its site (Eckel et al., 2011). It has been well established that modest sustained weight loss of 5–10% can reduce the risk of T2DM (Ahmed and Crandall, 2010) by decreasing IR, improving glucose tolerance and glycaemic control (Delahanty, 2002). Despite the established relationship between obesity and T2DM (Abdullah et al., 2010) the current model of care often concentrates on pharmacological interventions that may contribute to weight gain with incremental dose increases and hence increased cost of care (Hamdy, 2008). Despite treatment with

oral hypoglycemic agents (OHA), 50% of individuals require insulin therapy within 10 years of T2DM diagnosis (Turner et al., 1999). OHAs cannot abolish the progressive loss of β -cell (Fonseca, 2009) and drug therapy alone does not address the underlying lifestyle issues which fuel the development of T2DM.

Lifestyle interventions (LSI) are defined as any intervention that includes exercise, diet and at least one other component (e.g., counselling, stress management, smoking cessation) (Sumamo et al., 2011). LSI is a routinely recommended approach for primary prevention of T2DM but is applied less often once T2DM is diagnosed (Ades et al., 2015). Studies suggest that only 34% of individuals with T2DM ever see a registered dietitian (RD) and rarely achieve significant weight loss or improved fitness (Ades, 2015). Lack of referral and financial reimbursement together with the patients' poor perception of the impact of LSI have been identified as factors that lead to the under-utilization of LSI programs in the management of T2DM (Alameddine et al., 2013).

The Look AHEAD (Action for Health in Diabetes) study draws our attention to a possible paradigm shift in the management of T2DM by suggesting that T2DM can be reversed, its risk lowered and its complications delayed by implementing inexpensive, easy to use LSI that address obesity (Gregg et al., 2012). This alternative model of care

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focuses on body weight management, which is a root cause of T2DM. Weight loss results in improved glycaemic control by significantly improving hepatic insulin sensitivity, lowering intrahepatic lipids (Lim et al., 2011; Stanford et al., 2012), thereby reducing the requirement for medication and leading to decreased cost of care (Hamdy, 2008). Similar benefits are seen following weight loss with pharmacotherapy (Van Gaal and Dirink, 2016) and bariatric surgery (Yska et al., 2015) yet, LSI is found to be of lower cost and is a safer than the other modes of treatment (Yeh et al., 2016; Lawley, 2014; Lois and Kumar, 2008).

As a reflection of the global epidemic of obesity and associated T2DM there is greater emphasis placed on successful LSI programs. This study was designed to assess the impact of multiple LSI on diabetes care in an Indian population with T2DM within a typical outpatient clinic setting and assess the savings that might accrue through reductions in medication costs.

2. Methodology

A cohort of obese and overweight subjects over the age of 18 with a diagnosis of T2DM were identified from the clinic register of a private endocrinology practice in Mumbai, India. Following interview, 45 subjects with T2DM were enrolled onto an LSI program.

2.1. At baseline and to one year

Subjects underwent an intensification of LSI each week delivered by a dedicated RD.

- **Dietary counselling:** Participants were counselled using the ADA guidelines for management of T2DM (American Diabetes Association, 2011) using a stepwise approach of counselling and personalized, individualized and tailored meal plans.
- **Exercise counselling:** Participants were encouraged to increase daily activity levels and implement a bespoke exercise schedule with minimum target duration of 45 min, 6 days a week.
- **Education and monitoring:** Participants were trained to self-monitor fasting blood sugar (FBS) and post prandial blood sugar ([PPBS] post breakfast, lunch and dinner) twice weekly (weekday and weekend) and email/SMS results including details of food recall, exercise and weight using a template on a weekly basis to the educator. Education included hypoglycemia management and an awareness of adverse drug reaction (ADR) for the medications prescribed.

The goal provided to each patient was to lose 5–10% of current body weight. Supervision of glycaemic control was monitored and adjustments to medication made as deemed appropriate by the physician. Follow up site visits were planned for each patient at quarterly intervals (± 15 days). Participants were supported in this program for a period of one year, after which they were returned to routine care where, as per the clinic standard operating procedures, they were counselled to seek a consultation every 3 months and offered the weekly email contact as an optional paid service. Reiteration of lifestyle modification (LSM) is typically a component of every consultation in routine care.

2.2. At year five

Data were collected from records that were updated to October 2016. In order to collect data at year five for participants with poor compliance to clinic visits, telephone contact was made. Subjects were encouraged to attend clinic for a follow up visit, in order to assess their current status of T2DM. Data were collected over the telephone in instances where the patient was unable/unwilling to visit the clinic.

Criteria used to define responders to LSI were weight loss and reducing requirement of treatment based on weekly SMBG and quarterly HbA1c. The ADA definition of remission was used (Buse et al., 2009)

(Table 1). Other data collected included lipid levels, blood pressure (BP) and cost of medications.

2.3. Clinic support

Participants received care and support from one designated case manager who was a qualified and experienced diabetes educator (DE). In addition to co-ordinating with the physician for change in treatment, the diet and exercise recalls sent by the participant were reviewed and commented upon to achieve improved compliance to the diet and exercise plan. Participants could contact the DE as required. Email or telephone reminders were provided in cases of missed weekly contacts and to plan quarterly appointments with laboratory investigations. Laboratory investigations were individualized to patient requirement based on presence of other co-morbidities. In addition, to motivating the participants, educational resources and health tips were emailed on a weekly basis. Participants were encouraged to involve any carers in implementing the plan. If required the carers were also educated to assist the patient, to better manage and implement the LSI strategies. Support from carers predominantly included meal planning with options and tailoring to the patient's likes and dislikes. Each counselling session at the clinic was planned on a one to one basis and though recommended on a quarterly basis, could be planned as required.

2.4. Data collection

A number of varied data points were collected at baseline and follow up visits at one year post intervention, 5 years post intervention and through email contact (Table 2).

2.5. Data analyses

Analyses were performed using SPSS software for Windows (version 16.0, 2007, SPSS Inc, Chicago, IL). Data are presented as frequency (percentage) or Mean \pm SD. Independent Sample T test was used to compare difference in parameters between males and females. Paired sample T test was used to analyze the difference in parameters between onset, year one and year five. Cross tabulations were computed and analyzed using chi-square test to study associations. *p* value less than 0.05 was considered to be statistically significant.

3. Results

3.1. Participants' baseline characteristics

The baseline characteristics of 45 participants (30 males, 15 females) enrolled in the LSI program is provided in Table 3. Mean age was 45.1 ± 10.2 years and HbA1c 79 ± 4 mmol/mol ($9.4 \pm 2.5\%$), BMI 28.9 ± 4.8 kg/m² and the Asian classification for BMI was employed since all the participants were Indians (World Health Organisation, 2004). The majority of subjects (*n* = 26) had been diagnosed with T2DM for less than 1 year, with 17 subjects having the disease for over 5 years and only 2 subjects diagnosed over 10 years prior to enrolment. At baseline 43 subjects were treated with OHAs. Of these 31 subjects required two or less OHAs to treat their diabetes, 12 subjects required 3 or more OHAs and 3 subjects were being treated using a combination of OHA and insulin. Data for 41 participants (27 males, 14 females) were collected at year five. Two participants were lost to follow up and all attempts to contact them via email and telephone were unsuccessful. One participant died of cancer, while one was excluded as she underwent a pregnancy and delivered in early 2016. Table 4 provides a baseline comparison of characteristics observed between responders and non-responders to LSI.

Table 1
Definitions of diabetes remission (Buse et al., 2009).

Remission	Definition
Partial remission	Sub-diabetic hyperglycaemia (HbA1c) not diagnostic of diabetes [$< 6.5\%$], fasting glucose 5.6–6.9 mmol/l) of at least one year's duration in the absence of active pharmacologic therapy or ongoing procedures
Complete remission	Return to “normal” measures of glucose metabolism (HbA1c in the normal range [$< 5.7\%$], fasting glucose < 5.6 mmol/L) of at least one year's duration in the absence of active pharmacologic therapy or ongoing procedures.
Prolonged remission	Complete remission that lasts for more than five years and might operationally be considered a cure.

Table 2
Data points collected at different time points in the study.

Data Characteristics	At Baseline	Email/SMS contact	Follow up visits	At Year 1 and 5
Demographic data	X			
Food Preference	X			
Food Allergies	X			X
Smoking	X		X	X
Alcohol consumption	X	X	X	X
Medical history	X			
Duration of diabetes (yrs)	X			
Age of onset (yrs)	X			
Treatment:Diabetes	X	X	X	X
Concomitant conditions	X	X	X	X
Other Treatment	X	X	X	X
Anthropometric Data				
Height (cms)	X			
Weight (kgs)	X	X	X	X
BMI (kg/m ²)	X		X	X
Ideal Body Weight (IBW) (kgs)	X			
Laboratory Investigations				
HbA1c (%)	X		X	X
Lipids (mg/dl)	X		Optional	Optional
Liver Enzymes (SGOT,SGPT) (IU/L)	X		Optional	Optional
Other tests (optional: as per patient requirement)	X		X	X
Self-Monitoring of Blood Glucose (SMBG)		X		
Procedures				
Electrocardiogram (ECG)	X		X	X
Other test (optional: as per patient requirement)	X		X	X
Physical activity (Recalls)		X	X	X
Diet (Recalls)		X	X	X
Hospitalisation (if any)	X	X	X	X

3.2. Weight

Participants' mean weight loss from baseline at end of year one was 7.6 kgs and at year five was 6.4 kgs Significant weight loss was observed at year one ($p < 0.05$) with 26.8% ($n = 12$) achieving weight loss $\geq 10\%$, 20% ($n = 9$) achieving 5–10% weight loss and 44.4% ($n = 20$) achieving $\leq 5\%$ weight loss. 4 subjects (8.8%) gained between 1 and 3 kg at the end of year one. Weight regain was noted at year five across all three categories but continued to be significantly lower when compared to baseline. 9 subjects (21.5%) had weight higher than their original baseline weight at year five. The difference in mean weight from baseline to year five across the three original weight loss categories was 0.8 kgs ($\leq 5\%$ weight loss), 2 kgs (5–10% weight loss) and 12.2 kgs ($\geq 10\%$ weight loss).

3.3. HbA1c

Mean HbA1c (\pm SD) was 79 ± 4 mmol/mol ($9.4 \pm 2.5\%$) at baseline, 42 ± 1 mmol/mol ($6.0 \pm 0.5\%$) at year one and 48 ± 1 mmol/mol ($6.5 \pm 1.2\%$) at year five. Mean HbA1c reduced significantly at year one and year five compared to baseline for all

Table 3
Baseline Characteristics of participants enrolled in the study.

Characteristic	Total (%)	Male	Female
Number	45	30 (66.7)	15 (33.3)
Height (cms)	167.7 ± 8.4	171.8 ± 6.3	159.5 ± 5.5
Weight (kg)	81.6 ± 18.1	86 ± 19.8	72.8 ± 9.4
BMI (kg/m ²)	28.9 ± 4.8	29 ± 5.6	28.6 ± 3.0
18.5–22.9	3 (6.7)	3 (10)	0 (0)
23–24.9	4 (8.9)	3 (10)	1 (6.7)
25–29.9	21(46.7)	12 (40)	9 (60)
> 30	17 (37.8)	12 (40)	5 (33.3)
WC (cms)	98.1 ± 15.6	101.4 ± 17	91.7 ± 10.2
Age of onset (T2DM) (yrs)	43.2 ± 10	43.8 ± 8.5	41.9 ± 12.8
≤ 30 years	3 (6.7)	–	–
31–50 years	32 (71.1)	–	–
≥ 51 years	10 (22.2)	–	–
Age at intervention (yrs)	45.1 ± 10.2	45.4 ± 8.0	44.5 ± 13.9
≤ 30 years	3 (6.7)	–	–
31–50 years	29 (64.4)	–	–
≥ 51 years	13(28.9)	–	–
Duration of T2DM (yrs)	1.9 ± 2.7	1.4 ± 2.3	2.7 ± 3.3
< 1 year	26 (57.8)	–	–
1–3 years	5 (11.1)	–	–
3–5 years	6 (13.3)	–	–
5–10 years	6 (13.3)	–	–
More than 10 years	2 (4.4)	–	–
HbA1c at intervention mmol/mol (%)	79 ± 4 (9.4 ± 2.5)	81 ± 3 (9.6 ± 2.4)	75 ± 5 (9.0 ± 2.6)
Mild (6–7.99%)	15 (33.3)	–	–
Moderate (8–9.99%)	17 (37.8)	–	–
Severe (> 10)	13 (28.9)	–	–
Mode of treatment			
LSI only	2(4.4)	–	–
OHA only	40(88.8)	–	–
OHA and insulin	3(6.8)	–	–
Number of OHA			
0	2(4.4)	–	–
1	9 (20)	–	–
2	22 (48.9)	–	–
3	12 (26.7)	–	–
Hypertension	17 (37.7)	14(46.7)	3(20)
Dyslipidaemia	10 (22.2)	10 (33.3)	0(0)

Table 4
Baseline Characteristics of responders vs. non responders.

Characteristic	Responder	Non responder
Age (yrs)	44.9 ± 11	45.6 ± 8.4
Weight (kgs)	81.3 ± 18.3	82.5 ± 17.9
BMI (kg/m ²)	28.7 ± 5.0	29.3 ± 4.2
WC (cms)	97.3 ± 15.6	100.6 ± 16.0
Duration of diabetes (yrs)	1.06 ± 2.20	4.51 ± 2.70
HbA1c mmol/mol (%)	81 ± 5 (9.6 ± 2.6)	69 ± 1 (8.48 ± 1.37)
OHAs	1.83	2.50

subjects. Despite higher rates of failure, well controlled glycemia is observed at year five, which may be attributed to addition of pharmacotherapy in patients who failed remission.

3.4. Remission of T2DM

Twenty-four subjects (53.3%) reached the partial remission definition at year one while 8 (17.8%) subjects reached the complete remission definition. At year five, 11 (26.8%) subjects achieved partial remission while complete remission was sustained by 8 (19.5%) subjects.

Of the participants who reached the remission threshold, 26.7% ($n = 12$) attained it in the first 12 weeks following the start of LSI, 48.9% ($n = 22$) achieved it at between 12 and 52 weeks with one subject (2.2%) achieving remission beyond one year. 19 participants sustained remission for 3–5 years (42.2%), while 11.1% ($n = 5$) sustained remission for 1–3 years.

The duration of T2DM was 23 months with 57.8% ($n = 26$) having diabetes for less than 12 months. There was a significant inverse relationship at year one ($p = 0.005$) and year five ($p = 0.039$) between the rate of remission and duration of diabetes. Greater chance of remission was observed in participants who had T2DM for < 12 months than those with a duration of T2DM of 5 or more years ($p < 0.05$).

3.5. Pharmacological treatments

At the outset of the LSI program, 43 subjects were receiving oral hypoglycemic agents (OHAs) with 12 taking three or more OHAs. Subjects being treated with three or more OHAs were least likely to achieve remission from T2DM at the end of year one (6 out of 12) and were more likely to fail to sustain remission at the end of year five (9 out of 12). Of the three subjects receiving insulin, all had stopped insulin by the end of year one and had continued without insulin at the end of year 5.

At baseline hypertension (HTN) and dyslipidemia were documented as co morbidities for 17 and 10 subjects respectively. A reduction in the use of anti-hypertensive ($n = 3$, 7.3%) and lipid lowering agents ($n = 2$, 4.8%) was noted at year five.

3.6. Compliance with clinic visits

Attendance at quarterly visits to the clinic was calculated from year one to year five. 22 participants (49%) attended once or less during the year. 8 participants attended 2 appointments, 1 patient 3 of 4 yearly appointments and 12 subjects kept all 4 appointments. However poor compliance to visits did not influence the rate of remission ($p > 0.05$).

3.7. Cost of treatment

The cost of pharmacological agents for T2DM, HTN and dyslipidemia was calculated in this study. The average daily cost of treatment per day for all subjects at baseline was \$32/day which was reduced to \$9/day at the end of year one. At year five the average daily cost of treatment was \$16.5/day. Although higher than at the end of year one, spending at year five was lower than at baseline ($p < 0.05$). At the end of year one and year five, reductions in drug therapies translated into savings of \$188/year/patient and \$144/year/patient respectively versus baseline costs. The average 5 yearly savings in treatment costs were \$765/patient.

4. Discussion

This study demonstrates that remission of T2DM can be achieved and maintained for as long as five years by employing and implementing an LSI program in a real-world diabetes clinic. 35 (78%) subjects achieved diabetes remission one year after intervention with 21 subjects (51%) still in remission at year five. A mean weight loss of 7.6 kg (7%) was associated with reaching partial remission threshold for 24 subjects (53.3%) and complete remission threshold in eight subjects (18%) at year one. At year five, despite a gradual increase in

weight from that of the end of year one, 11 subjects (26.8%) continued to be in partial remission and 8 (19.5%) in complete remission demonstrating the continued benefits of initial weight loss.

The findings of this study are broadly in line with other similar studies. Wing et al. (1987) noted the association between higher weight loss and greater reductions in HbA1c (Wing et al., 1987). In the Look AHEAD (The Look AHEAD Research Group, 2014) study participants randomized to intensive LSI achieved a weight loss of 8.5% with an 11.5% absolute rate of remission from diabetes in the first year. The prevalence ratio of any form of remission was observed to be highest during the first year when maximum reduction in weight was observed. In this study, weight regain ensued at the end of the first year with weight loss of only 4–4.7% being maintained for the remainder of the study. The absolute rate of remission subsequently fell to 7.3% from 11.5% at the end of 4 years (The Look AHEAD Research Group, 2014). Steven et al. (2013) compared the rate of remission with magnitude of weight loss (Steven et al., 2013). Remission of diabetes was observed in 80, 63 and 53% of those with > 20, 10–20 and < 10 kg weight loss (Steven et al., 2013). Similar findings were noted in our study population where the rate of remission was 42%, 15% and 24.5% in participants who experienced weight loss $\geq 10\%$, 5–10% and < 5% respectively at year one. At year five weight regain was experienced in all categories and failure of remission (relapse) was also higher with remission dropping to 19.5% vs. 42%, 9.7% vs. 15% and 21.9% vs. 24.4%. The lowest percent relapse was observed in the participants who lost the maximum weight at year one and regained the least weight at year five thus implying the relationship between weight management and remission of T2DM.

Together with remission of T2DM, there was also a decline in the requirement for pharmacological treatments. Of the two participants who were able to discontinue treatment for dyslipidemia, one patient reported a weight loss of $\geq 10\%$ with the other achieving a weight loss of $\leq 5\%$. The three participants who were able to discontinue treatment for HTN had lost $\geq 10\%$ weight.

Dyslipidemia and HTN along with T2DM are known to be strong predictors and significant contributors to CVD morbidity and mortality (Martín-Timón et al., 2014; Tacer and Rozman, 2011). The possibility of remission of all these three chronic conditions holds great promise for preventive cardiac care and may have significant economic impact on the resources allocated for prevention and treatment of CVD (World Economic Forum, 2014).

The failure of remission at both year one and year five was highest in participants with a longer duration of diabetes (5–10 years). The maximal number of subjects achieving remission of T2DM was observed in those who had a diagnosis of diabetes for < 1 year. The remission rate at year one in participants with shorter duration of diabetes was 55.5% ($n = 25$) and 39% ($n = 16$) at year five. Feldstein et al. studied the effects of weight loss in participants who were newly diagnosed with T2DM and concluded that weight loss after recent diagnosis predicted improved glycemic and blood pressure control even in the face of weight regain (Feldstein et al., 2008), thus highlighting that the therapeutic advantages achieved through weight loss are more successful early after the diagnosis is made.

Current concepts of T2DM management suggest that the progressive nature of T2DM leads to a steadily increasing requirement of OHAs over time (American Diabetes Association, 2013). The UKPDS demonstrated the sequential requirement for additional OHAs to maintain glycemic control (Yu et al., 2007). Three years post diagnosis, 50% participants required more than one pharmacological agent and by nine years more than 75% participants required multiple agents to achieve glycemic control (Yu et al., 2007). Maximum failure of remission was noted in participants who were being treated with more than three OHAs at the time of intervention, despite weight loss. This emphasizes the importance of early LSI following diagnosis and the need to capitalize on the short window available to physicians to opt for LSI as the first line of treatment. Therefore, maximizing LSI programs particularly in

patients with a recent diagnosis of T2DM might be expected to maximize the opportunities of inducing remission from T2DM, reduce associated co-morbidities and maximally reduce healthcare costs (Turner et al., 1999).

In our study, participants who failed to achieve remission had higher treatment expenses at baseline itself when compared to participants who achieved remission. Higher baseline expenses in participants who failed remission can be attributed to the requirement for multiple agents in order to achieve glycemic control owing to a longer duration of T2DM and associated co-morbidities. Prevalence of dyslipidemia in the group that failed remission was higher (30%) compared to the group that achieved remission (20%). Prevalence of hypertension was similar in both groups (40% vs. 37%). In the group that achieved remission the average daily spending on antihypertensive treatments and dyslipidemia remained similar from baseline to year one and year five, however in the group whose diabetes persisted, the cost nearly doubled at the end of five years.

A majority of participants were able to sustain remission for 3–5 years while decreasing the average HbA1c by 3.4% and achieving weight loss of 7.7% and 5.1% at year one and year five respectively. Hamdy (2008) states that a ~1% drop of HbA1c leads to cost savings of \$776/patient/year (Hamdy, 2008) while Yu et al. estimated that 1% weight loss in participants with T2DM lead to a total healthcare saving of \$213/patient/year, and the diabetes-related healthcare cost saving of \$131.31/patient/year (Yu et al., 2007). Considering the cost savings from both reduced requirement of treatment (3–5 years) improved HbA1c and weight loss, LSI does emerge as potential cost-effective treatment strategy, although the cost of health care professional time in providing additional support for patients would also need to be factored into calculations.

One of the features of this LSI program was close monitoring in the first year by a dedicated DE. A number of studies have proven that availability of an extended care model during the weight maintenance phase would continue to help people lose weight and avert weight regain (Dalle Grave et al., 2005). However, no significant relationship was observed between continued clinic/email contact and maintenance of weight loss and therefore remission, suggesting that significant improvements in weight management can be undertaken and maintained by individuals in their usual environment with minimal or no professional support (Steven et al., 2013).

4.1. Implications

Like other studies (Hamdy, 2008; Ades, 2015; Gregg et al., 2012; Lim et al., 2011; Karter et al., 2014; Mottalib et al., 2015; Steven et al., 2016; Bynoe et al., 2015; Barnard and Lattimore, 1982) this study reveals that T2DM can be successfully managed by using simple lifestyle measures which are safe, efficacious and cost effective. The success of this treatment option lies in motivating and encouraging participants to engage, actively in self-care activities that promote lifestyle changes rather than depending on medical therapy. Despite the tailored and individualized care made available to every patient, this model of care was planned and executed within the regular framework of care, suggesting that this clinic based model of care, can be translated successfully to the routine clinical practice.

South Asians are genetically more prone to developing T2DM, at a lower BMI (Misra and Shrivastava, 2013) and a younger age (United Kingdom Prospective Diabetes Study Group, 1994), and therefore more likely to develop complications (Kaveeshwar and Cornwall, 2014). In India, due to lack of social insurance policies, 85–95% of all healthcare costs are borne by the individual with people from the lower income groups bearing the greatest burden (Singh, 2013). The high cost of treatment and poor affordability to care may lead to higher incidence of non-compliance especially in the poorer sections of the society (World Health Organisation, 2016) exposing them to increased risk of diabetes-related complications and added burden of disease (Kumpatla et al.,

2013).

This study reveals the implementation of an LSI program into routine diabetic practice results in significant weight loss and remission of diabetes in the majority with benefits persisting beyond the one year of active intervention. The program also is associated with the reduced drug costs that may be expected to make such programs cost effective. For a developing country like India, application of LSI, may be expected to translate into improved population health, improved economic productivity and lowered economic burden of disease (Yesudian et al., 2014).

4.2. Limitations

The major limitation of this study is the small and highly selected sample size. The subjects were selected after interview from a larger clinic patient pool and confirmed their willingness to participate in LSI. Therefore, this introduces a selection bias which may limit the applicability of this approach in a wider clinical setting. That said however, the results of this study are valid in that remission of T2DM can be achieved with lifestyle support.

In this study, impact of weight loss has been studied only in reference to hypertension and dyslipidemia in addition to T2DM. Inclusion of parameters that would have enabled us to study the impact of weight management on cardiovascular disease, sleep apnea and non alcoholic-fatty liver disease (NAFLD) would have been useful but were not collected.

A record of email/SMS data was maintained between baseline and year one only if change in pharmacotherapy was advised. Assessing the relationship between remission and frequency of monitoring during the intensive period of treatment would have been worthwhile. These data would have been valuable for new SMBG users (< 1 year) as increased frequency of monitoring in new users has been associated with significant decrease in HbA1c irrespective of line of treatment advised (LSI or pharmacotherapy) as opposed to older users where the benefits of SMBG are observed only in participants managed with pharmacotherapy (Karter et al., 2006).

We are unable to comment on cost effectiveness of the intervention, as we did not collect data on costs of physician and diabetes educator costs, email/SMS service, home blood glucose monitoring, laboratory investigations, hospitalizations (if any), travel, paid exercise sessions (if any), and loss of working days for physician visits and investigations (Rayappa et al., 1999).

5. Conclusion

This study demonstrates that diabetes remission can be achieved and maintained for as long as five years after employing a one year LSI program in a primary outpatient clinic setting (Lean et al., 2018). The study suggests that maximal benefits of such a program are gained with the LSI intervention commencing as early as possible after a diagnosis of T2DM is made and that LSI results in substantial cost savings in drug treatments.

Declaration of interest

The paper is based on work submitted in partial fulfilment of the MSc Diabetes at the University of South Wales.

Conflicts of interest

All authors declare that they have no conflict of interest.

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