Effectiveness of A Theory-based Intervention to Promote Diabetes Management Behaviours Among Adults with Type 2 Diabetes in Iran: A Randomized Control Trial

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Abstract

Background: The prevalence of diabetes has been increasing, imposing massive costs on nations. Diet and physical activity are recommended for diabetes management. Evidence suggests theory-based interventions are more efficacious than non-theory approaches. This study aimed to test the effectiveness of an integrated theoretical model-based intervention to encourage compliance for low-fat food consumption, carbohydrate counting, and physical activity in adults with type 2 diabetes. Methods: A 4-week parallel randomized control trial was conducted in Iran. Data were collected using a self-report questionnaire at baseline and 8-weeks post-intervention. This survey assessed the Theory of Planned Behaviour (TPB) constructs of attitude, subjective norm (others' approval), and perceived behavioural control (PBC). We also assessed risk perceptions (motivational) and planning (volitional) from the Health Action Process Approach (HAPA). Furthermore, weight, body mass index, triglyceride (TG), and LDL-cholesterol were measured. Results: For both low-fat food consumption and physical activity, only planning revealed a significant improvement over time for intervention rather than control participants (F=8.78, p[?]0.001 for low-fat vs. F=11.26, p[?]0.001 for physical activity). For carbohydrate counting, significant effects were found for behavior (F=4.37, p=0.03), intention (F=8.14, p[?]0.001), PBC (F=7.52, p[?]0.001), and planning (F=4.54, p=0.03), reflecting improvements over time in the intervention participants compared to controls. Further, the effects of the intervention on behavior were partially mediated via participants' degree of planning (B=0.10, SE=0.06, CI=0.01 to 0.26). The serum TG level was significantly reduced from pre to post-intervention for intervention rather than for control participants (F=18.69, p[?]0.001). Conclusions: This intervention was promising for carbohydrate counting but did not show improvements for low-fat diet nor physical activity. Given the improvement in psychological measures and self-reported behaviour for carbohydrate counting, coupled with the findings for TG, future research is needed to demonstrate longer-term improvements. Current theory-based educational strategies can be adopted for the management of carbohydrate intake in diabetes.

Introduction

Diabetes is a significant health challenge and dramatically growing worldwide, especially in low-and middle-income countries (Guariguata et al., 2014). Diabetes prevalence in Iran is estimated to be 10.1% in 2015, which translates to 4.6 million adults (20-79 years) with diabetes (IDF, 2015). Uncontrolled diabetes in the long-term can progressively lead to complications, including retinopathy, nephropathy, neuropathy, and cardiovascular effects (Alberti and Zimmet, 1998, IDF, 2013). Maintenance of blood glucose, cholesterol, and blood pressure to near normal levels can delay or prevent diabetes complications (IDF, 2013). The American

Diabetes Association (ADA) recommends lower saturated fat intake in people with diabetes. It considers carbohydrate monitoring using carbohydrate counting as a critical strategy in the management of blood glucose (ADA, 2019). Furthermore, physical activity is an influential component in diabetes management (Clark et al., 2004, Wheeler et al., 2012). Definitions of the included behaviours are as follows: Low-fat food/meal consumption was defined as "reducing saturated fat intake by low-fat dairy products, using polyunsaturated and monounsaturated oils [plant based], avoiding fried foods and trimming the fat from meat [Lean meat]" (Diabetes Australia, 2015). Carbohydrate counting was defined as "identifying which foods contain carbohydrate, then assessing how much carbohydrate a serving of food (or an entire meal) contains concerning recommendations and if you use insulin, match with insulin dose" (ADA, 2017; Joslin Diabetes Center, 2019) and physical activity was defined as "engaging in moderate physical activity for at least 150 minutes per week [half an hour/day, most of the days of week]" (Diabetes Australia, 2015).

Background

Behavioural interventions have demonstrated effectiveness in diabetes management, and theory-based interventions are more efficacious than non-theoretical approaches (Michie and Abraham, 2004). Several theories have been used to inform health behaviour change, including the Theory of Planned Behaviour (TPB) (Ajzen, 1991) and the Health Action Process Approach (HAPA) (Schwarzer, 2008). According to the TPB, a person's behaviour is a function of intention to engage in the behaviour. In turn, the intention is directly determined by attitude (positive or negative evaluation of the behaviour), subjective norm (perceived pressure to perform a behaviour), and perceived behavioural control (PBC; perception of control over performing the behaviour, also said to influence behaviour directly). The direct TPB constructs also have a belief basis with advantages/disadvantages underlying attitude, important specific referents underlying subjective norm, and barriers/facilitators underlying PBC. The recent debate about the utility of the TPB in health psychology applications (Sniehotta et al., 2014) highlights the need to test the validity of the TPB. A recent meta-analysis demonstrated the effectiveness of TPB-based interventions in people with type 2 diabetes (T2D) (Steinmetz et al., 2016), with the effect size of 0.5 (CI=0.24 to 0.75) for behaviour. A TPB-based intervention among older T2D adults with cardiovascular disease found an extended TPB (with planning as an extra measure) intervention effective for improving physical activity but not healthy eating (White et al., 2012).

The HAPA is another theoretical framework focusing on motivational and volitional processes in health behaviour change (Schwarzer, 2008). Preintentional (motivational) processes target behavioural intention, and post intentional (volitional) processes lead to actual behaviour change. Perceived risk and outcome expectancies drive contemplation in the motivation phase, with self-efficacy also influencing intention. Schwarzer considers a minimum level of perceived risk necessary for the initiation of contemplation regarding the benefits of behaviour and one's competence to perform the behaviour. For intentions to translate into behaviour, a volitional phase involving planning occurs, also underpinned by self-efficacy.

Moreover, perceived risk is a core motivational concept in many health behaviour theories, such as the Health Belief Model [HBM] (Rosenstock, 1974). It has been included in TPB studies (Brewer et al., 2007) to influence motivation for the initiation of mental preparedness for health change. Typical inclusions of risk perception measurement are risk severity (feeling the seriousness of contracting an illness or of leaving it untreated) and risk susceptibility (beliefs about the likelihood of getting a disease). Risk severity has been effective in predicting hemoglobin A1C (HbA1c) reductions in T2D participants (Daniel and Messer, 2002) and those with higher perceived severity and susceptibility were more adherent to self-care behaviours (Ayele et al., 2012, Tan, 2004).

In addition, planning has been suggested as a key volitional variable in behaviour change interventions (Sniehotta et al., 2005b, Norman and Conner, 2005), especially as it can mediate the intention-behaviour relationship (Norman and Conner, 2005, Luszczynska, 2006, White et al., 2012). According to the HAPA, the intention should be transformed into detailed instructions on how to perform the intended behaviour (action plans), which is necessary to prevent impulsive actions. Further, maintaining the initiated behaviour should be protected from barriers and obstacles by consideration, for example, of effective coping strategies (coping plans). It is believed that, via planning, individuals form a subjective instance of the target situation, which makes the target cue related to the situation more accessible and critical conditions easily identifiable (Gollwitzer, 1999). Planning has been previously assessed via action planning (enabling practical behaviour initiation via specifying a time, location, and how to perform the behaviour (Leventhal et al., 1965)) and coping planning (overcoming barriers by utilizing coping responses to deal with difficulties (Sniehotta et al., 2006)). Similarly, objective measures such as weight, body mass index (BMI), triglycerides (TG), and LDL-cholesterol (LDL-c) are essential components of comprehensive diabetes evaluation (ADA, 2019).

In a previous formative qualitative study among T2D (Blinded for review) we showed the inclusion of the standard TPB constructs (attitude, subjective norm, PBC), as well as risk perceptions and planning factors from the HAPA, which appeared viable as the focus of a behaviour change intervention among this cohort. To our knowledge, there is no TPB-based intervention among diabetes patients in Iran. Thus, the present study employed an integrated theoretical framework for informing and evaluating a behavioural intervention to promote low-fat food consumption, carbohydrate counting, and physical activity, three critical behaviours in diabetes management. We hypothesized that intervention participants would demonstrate an improvement compared to control participants at the end of the study, for (a) attitude, subjective norm, perceived behavioural control, intention, planning and risk perception for the three diabetes management behaviours, (b) the self-reported diabetes management behaviour, and (c) the behavioural indicators of weight, BMI, TG, and LDL-c.

Methods

A parallel randomized control trial was designed to assess the effectiveness of a 4-week intervention based on the integrated theoretical model in adults with T2D. The factors and underlying beliefs identified for intervention focus were based on an initial, formative qualitative study among 30 T2D participants. Ethical approval was obtained from the Ethics Committee of "Blinded for Review". Given there are no national dietary or educational guidelines for diabetes in Iran, target behaviours were adapted from international guidelines such as the American Diabetes Associations (ADA, 2017), Diabetes Australia (Diabetes Australia, 2015), and the Joslin Diabetes Center (Joslin Diabetes Center, 2019). The study was registered with the Iranian Registry of Clinical Trials (IRCT2013040912961N1).

Participants

T2D adults were recruited from the Iranian Diabetes Society (IDS), Tehran, Iran. Inclusion criteria were adults (aged 25-60 years) diagnosed with T2D for at least two years on lipid-lowering medications (e.g., Statins, Nicotinic acid). They had taken part in regular diabetes education classes, including carbohydrate counting. People with diabetes complications (retinopathy, nephropathy, and neuropathy), CVD (cardiovascular diseases) or other conditions that may prevent class attendance, taking medications that affect lipid levels such as antipsychotics (e.g., Clozapine), and alcohol drinkers (consume beer, wine, liquor, or hard liquor beverages at least once per week for a minimum of 6 months (Lee et al., 2007)) were ineligible.

Design and Procedure

The present study employed a 2 (Condition: intervention vs. control) by 2 (Time: preintervention vs. 8-week post-intervention) mixed measure design, with Time a repeated measure factor. A power calculation was undertaken using G*power 3.1 software (Faul et al., 2009), whereby a repeated measure MANOVA is used with a power of 80%, an effect size of 0.4 and $\alpha=0.05$, yielding a minimum sample size required of 97 participants (that was minimally exceeded following exclusions, etc.). A total of 220 adults diagnosed with T2D were selected from a list provided by IDS using permuted block randomization (a 1:1 allocation ratio) and contacted. As a result, the exclusion could only take place after the randomization process. Permuted block pattern was obtained via an Internet-generated pattern with a block size of 8. The participant's list was provided by IDS staff, and the researchers were blinded. Figure 1 shows the flow of participants in the study. Written informed consent was obtained from each participant before the experiment. The study conforms to CONSORT guidelines (Schulz et al., 2010) (see Supplementary File 1).

Control Group

Participants in the control group completed pre- and post-intervention measures but received no intervention. They were offered one month of nutrition counseling after completion of the study.

Intervention Group

The intervention participants attended weekly 2-hour group-based intervention classes (each comprising 10 to 12 individuals) over four weeks, facilitated by two nutritionists. No outside of class contact was initiated between participants and educators during the study (see Table 1 for intervention strategies).

Measures

At Time 1, one-week before the intervention, participants completed a demographic questionnaire at arrival, then via a face-to-face interview by a trained health care provider completed an integrated questionnaire. Bodyweight and height were measured, and fasting blood lipids were assessed (Table 2). Time 2 (follow-up) measurements were performed eight weeks post-intervention during which time the integrated questionnaire measures were completed, weight and height measurements repeated, and lipid profile determined. While HbA1c would have been a desirable measurement for this study, we were unable to measure HbA1c since the measurements were performed eight weeks after the intervention. HbA1c is measurable after three consecutive months. Of the pre-intervention individuals, 107 (control, n =54; intervention, n =53) participated in all sessions and completed second measurements at week-8 (Figure 1).

The questionnaires were constructed broadly according to guidelines and examples outlined in previous research (Ajzen, 1991, Sniehotta, 2009, Schwarzer, 2008), with some negatively-worded items to reduce response bias. (see Table 3). The first draft questionnaires were translated from English into Persian under the supervision of an expert panel (11 Professors of nutrition, psychology, and health promotion) familiar with both Persian and English. The content validity of questionnaires was evaluated by a content validity index (CVI) and content validity ratio (CVR) and satisfactory scores (>0.82 and >0.75) for all measures. The questionnaires were then completed by five individuals with T2D to assess wording and their comprehension of items. The integrated questionnaires are available as supplementary (Supplementary File 2-4).

Data Analysis

The impact of the intervention across all three behaviours was assessed using 2 (intervention, control) × 2 (pre, post-intervention) MANOVAs. The integrated model constructs were considered as predictor variables for low-fat food/meal consumption, carbohydrate counting, and physical activity. In another MANOVA analysis, BMI, weight, TG, and LDL-c were considered as predictors to show the effects of the intervention on clinical and biochemical outcomes. Mediation analyses were also conducted to assess whether any of the (significant) extended TPB variables mediated the impact of the intervention on behaviour. α was set at 0.05 as the significance level. Baseline differences for age, gender, education level, job, marital status, years since diagnosis, weight, height, BMI, TG, and LDL-c were examined by Chi-square and independent t-tests.

Results:

The demographic characteristics of participants and baseline measures are shown in Table 2. The majority of participants were female (65.3%), full-time employees (53%), and married (90.3%). The mean age of the participants was 49.4 years±SD=6.15 in the control group and 48.05 years ±5.69 in the intervention. No baseline differences were observed in any variables. The mean number of years since diagnosis was 5.85 years (SD=2.89; range=2-14 years).

To assess any baseline differences for the integrated model measures, MANOVAs revealed no significant differences between groups (intervention or control) on the constructs for all three behaviours. Intention-to-treat analysis showed similar findings to those with the full participation of the study.

For the 2×2 MANOVA analysis, the between-subject factor was the intervention condition (intervention vs. control), and the within-subject factor was the time (Time 1: pre-intervention and Time 2: 8 weeks post-intervention). The integrated model variables and behaviour were entered as dependent variables (see Tables 4-7 for Ms, SDs, and significance levels).

Impact of Intervention on Low-fat Food Consumption

No significant Condition effects were observed for low-fat food consumption. There were, however, significant Time and Time by Condition effects: $\Phi(11,80)=3.01$, $\pi=0.002$, *παρτιαλ* $\eta^2=0.29$ and $\Phi(11,80)=2.65$, $\pi=0.006$, *παρτιαλ* $\eta^2=0.26$, respectively. Univariate results revealed a significant Time effect for risk severity with a significant increase for risk severity over time. There was no significant Time by Condition effect, except for planning, with a significant increase for planning scores over time in the intervention group, but not the control condition.

Impact of Intervention on Carbohydrate Counting

For carbohydrate counting, there were no significant main effects for Condition, but significant Time and Time by Condition effects with$\Phi(11,80)=3.67$, $\pi=0.000$, *παρτιαλ* $\eta^2=0.33$ and$\Phi(11,80)=3.21$, $\pi=0.001$, *παρτιαλ* $\eta^2=0.30$, respectively. Univariate Time effects showed significant results for behavior attitude, risk severity, and planning,which all increased over time. Further, significant Time by Condition effects was observed for behaviour, intention, and planning. Pairwise comparisons for the simple effects of time within the intervention conditions were then conducted. Participants in the intervention condition revealed significant increases in behaviour,intention, PBC, and planning, at follow-up compared to pre-intervention. There were no significant changes in the control condition across time on these constructs.

Mediation Analyses for Carbohydrate Counting

As participants in the intervention condition showed significant improvement over time for carbohydrate counting, a mediation analysis (Hayes, 2013) was conducted to assess whether the integrated model variables mediated the impact of the intervention on carbohydrate counting. In addition to pre-intervention carbohydrate counting behavior, all potential mediators, along with Condition, were entered into the model. The direct effect of Condition on behavior was significant, $B=0.54$, $SE=0.14$, $p<0.01$. Bootstrapping analyses resulted in the total significant mediated (indirect) effect as $B=0.26$, $SE=0.12$, $CI=0.01$ *to* 0.51 . The indirect effect was significant only via planning, $B=0.10$, $SE=0.06$, $CI=0.01$ *to* 0.26 . Further, inspection revealed that, after the inclusion of potential mediators (integrated model variables), the direct effect of the intervention on carbohydrate counting behaviour remained significant, $B=0.37$, $SE=0.16$, $CI=0.03$ *to* 0.71,indicating a partial mediation effect.

Impact of Intervention on Physical Activity

For physical activity, there were no significant effects for Condition but significant effects for Time and Time by Condition,$\Phi(11,80)=4.01$, $\pi=0.000$, *παρτιαλ* $\eta^2=0.35$ and$\Phi(11,81)=3.83$, $\pi=0.000$, *παρτιαλ* $\eta^2=0.34$, respectively. For Time, there were significant increases for intention, attitude, risk susceptibility, and risk severity. There was a single significant Time by Condition interaction for planning whereby intervention participants indicated a significant improvement over time, with no significant change in the control condition.

Effects of Intervention on Anthropometric Measures and Lipid Profiles

Weight, BMI, TG, and LDL-c changes were assessed by a 2 (condition: intervention, control) x 2 (time: pre, post-intervention) MANOVA. There were significant main effects for Time and Time by Condition,$\Phi(1,92)=4.16$, $\pi=0.002$, *παρτιαλ* $\eta^2=0.19$ and$\Phi(1,92)=4.81$, $\pi=0.001$, *παρτιαλ* $\eta^2=0.21$,respectively. Univariate results of Time indicated that TG increased significantly. The Time by Condition findings showed a significant effect on TG. There was a significant reduction of TG within the intervention condition with a significant reduction of approximately 10 mg/dl over time but no significant effect in the control condition.

Discussion:

The current study tested the utility of an intervention informed by an integrated theoretical model to promote low-fat food consumption, carbohydrate counting, and physical activity among adults with T2D in

Iran. This theory-based intervention could be adopted by chronic disease health care professionals. Based on the results of earlier qualitative formative research among the target population (Blinded for review), the intervention focused on constructs from the TPB and risk perceptions and planning factors from the HAPA. To our knowledge, this study comprises the first formal evaluation of a theory-based intervention to promote carbohydrate counting - a critical behaviour in diabetes management. The results suggest that the intervention was successful in changing behaviour and cognitions related to carbohydrate counting, showing some support for the integrated model to inform behaviour change in this context. However, it did not produce the expected changes for either low-fat food consumption or physical activity. The intervention was only successful in promoting the volitional construct of planning, but behaviour and other cognitions remained unchanged. This may be due to the nature of diabetes as a disease highly concerned with nutrition behaviours such that people already associate a diabetes diagnosis with a need to address any unhealthy eating patterns (Yannakoulia, 2006) .

For carbohydrate counting, the intervention showed promise by significant increases in behaviour, intention, PBC a,nd planning for intervention participants over time compared to control participants, with the improvements in carbohydrate counting behaviour at least partially due to enhanced planning. These findings emphasize the importance of including planning as a self-regulatory component in behavioural interventions, reinforcing assertions that the impact of cognitions on behaviour is mediated by planning (Norman and Conner, 2005, Sniehotta et al., 2005a, Gellert et al., 2012). There were no improvements over time among intervention participants for the motivational phase constructs of attitudes, subjective norm, and risk perceptions, but there was a significant change for PBC. This highlights the importance of control perceptions and the need to consider barriers to performance at both motivational and volitional stages of decision making for carbohydrate counting.

The observed differences for carbohydrate counting, as opposed to low-fat food consumption, may be due to the specificity of the carbohydrate counting behaviour for diabetes management and to the short-term acute symptoms resulting from non-compliance (leading to abnormal blood glucose and, consequently, clinical outcomes). Further, participants had completed the study inclusion requirement of diabetes education, incorporating carbohydrate counting training. They so were at least primed as to the importance and positive benefits of this crucial diabetes management behaviour.

For physical activity, intervention participants showed an improvement in their degree of planning for physical activity compared to control groups but no other cognitions or activity behaviours. These findings are in contrast to other TPB-related studies showing it to be an effective basis for a physical activity behaviour change intervention among adults with T2D (White et al., 2012). The current study may have faced challenges in promoting physical activity due to: (a) most participants were females who are culturally less involved in physical activities, especially outdoor exercise, and (b) >60% of participants had full-time jobs. The commute in Tehran is often 3-4 hours/day, both barriers which may benefit from direct targeting in future interventions.

The intervention significantly reduced TG levels by approximately 10 mg/dl but had no effects on LDL-c, weight, and BMI. Low-carbohydrate diets have been shown to reduce TG rather than LDL-c (Mahan et al., 2012, Santos et al., 2012). As the only behaviour change observed in this study was for carbohydrate counting. Because carbohydrate counting restricts carbohydrate intake explicitly, it seems reasonable to relate the reduction of TG to carbohydrate counting behaviour. Congruently, a meta-analysis by Santos et al., showed that low-carbohydrate diets did not affect LDL-c (Santos et al., 2012).

Strengths and Limitations

The study's strengths include the strong theory base of the intervention informed by an initial pilot study (see Blinded for review) and the mapping of these identified constructs on the intervention content. Further, this study provided one of the first theory-based interventions tackling the fundamental diabetes management behaviour of carbohydrate counting. It offered a test of the utility of the integrated theoretical model in informing health behaviour change in a cultural context where there is a dearth of theory-based health behaviour change interventions for T2D adults. Additional strengths were RCT design and the use of face-to-face interviews by trained health care providers allowing participants to check their understanding of the questions posed, likely improving the reliability of responses.

The relatively small sample size and lack of objective measurements of HbA1c and fasting blood sugar (FBS) is a limitation of the current study. FBS and HbA1c are common outcome measures in diabetes. FBS fluctuates in a short period, and regular test are required for judgment purposes. With respect to limited resources and participants' possibility of nonattendance for regular visits, we did not measure blood sugar. However, HbA1c changes are measurable after three months. Our post-intervention measurements were performed two months following the latest intervention session, due to time restrictions. Thus, we thought that two months might not accurately demonstrate the effects of TPB intervention on HbA1c.

Our post-intervention measurements were scheduled to be only performed on one occasion, two months post-intervention. Besides, study participants were all IDS members. These individuals are usually highly motivated about their diabetes management, bringing into question the generalizability of the findings to other adults diagnosed with T2D not aligned with a national diabetes organization.

Future research directions

Further research is needed to confirm the present findings, especially for carbohydrate counting and longer-term follow-up designs to assess other biochemical outcomes to validate self-reported behaviour. Longer-term designs, potentially integrated into health care clinics, would also be useful to check for intervention effects given common health complications and to establish the cost-effectiveness of behaviour change interventions in this context. Also, the utility of an integrated theory intervention approach for other key self-management practices such as self-monitoring of blood glucose and medication adherence should be assessed. Considering the growing prevalence of T2D in adolescents and children, further studies are needed to promote diabetes management behaviours in these age groups including parental adherence to carbohydrate counting and individuals diagnosed with type 1 diabetes (Kawamura, 2007, Scavone et al., 2010, Bell et al., 2014).

Conclusion:

Overall, the present study provided support for the utility of an intervention informed by an integrated theoretical model, incorporating aspects of both the TPB and the HAPA, targeting a critical behaviour (i.e., carbohydrate counting) for a clinical population of individuals with T2D. These results were encouraging not only in improving cognitions and showing promise, especially for constructs in the volitional phase of decision making, but also self-reported behaviour and a biochemical outcome. The intervention did not support a change in low-fat food consumption nor physical activity. Further research is needed to assess the more prolonged-term effects of interventions with a focus on carbohydrate counting and to attain generalized adherence to key management behaviours among this at-risk group to reduce the negative health consequences for people with a T2D diagnosis.

Relevance to clinical practice:

Health care staff including nurses, dietitians, diabetes educators, general physicians as well as specialists can use current health promotion approaches for the management of carbohydrate intake as a diabetes-specific behaviour, especially as they potentially render clinical benefits (i.e. reduced TG).

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