

Effectiveness of therapeutic patient education interventions in obesity and diabetes: A critical systematic review and meta-analysis of randomized controlled trials

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Abstract

Diabetes mellitus (DM) and obesity account for the highest burden of non-communicable diseases. There is increasing evidence showing therapeutic patient education (TPE) as a clinically and cost-effective solution to improve biomedical and psychosocial outcomes among people with DM and obesity. The present systematic review and meta-analysis presents a critical synthesis of development of TPE interventions for DM and obesity and the efficacy of these interventions across a range of biomedical, psychosocial and psychological outcomes.

A total of 54 of these RCTs were identified among patients with obesity and diabetes and were thus, qualitatively synthesized. Out of these, 47 were included into quantitative synthesis. There was substantial heterogeneity in reporting of these outcomes ($I^2= 88.35\%$, $Q= 317.64$), with significant improvement (SMD=0.36, 95% CI: 0.23 to 0.49) noted in biomedical outcomes in the intervention group. The effect sizes were comparable across interventions delivered by different modes and delivery agents. These interventions can be delivered by allied health staff, doctors or electronically as self-help programs, with similar effectiveness ($P < 0.001$). These interventions should be implemented in healthcare and community settings to improve health of patients suffering from DM and obesity.

Keywords: diabetes mellitus, obesity, meta-analysis, patient education, self-management, disease management.

Introduction

Obesity and diabetes mellitus (DM) account for the highest burden of non-communicable diseases. Recent meta-analyses revealed that the prevalence of central obesity globally is around 41.5% (95% CI 39.9–43.2%) using pooled data from 288 studies with over 13 million participants [1]. Obesity is also highly comorbid with type 2 DM with a prevalence of 8.5% among adults around the globe [2]. The public health, and socioeconomic impact of these disorders are immense. Reports by the American Diabetes Association estimate the economic costs of the DM at 327 billion USD including the direct medical costs and indirect productivity costs [3]. While the costs of obesity in the US alone are estimated at 1.72 trillion USD including \$480.7 billion in direct health care costs and \$1.24 trillion in indirect costs [4]. The high prevalence, morbidity and mortality and socioeconomic costs associated with these metabolic disorders warrant innovative solutions to deliver sustainable and equitable healthcare across the globe.

Studies have shown the impact of therapeutic patient education (TPE) as a clinically and cost-effective solution to improve biomedical and psychosocial outcomes among people with metabolic disorders [5-9]. The primary aim of TPE is to help people with different disorders understand the nature of their disease and empower them with resources to make informed decisions and self-manage their symptoms and prevent further complications [10]. TPE is also important to develop an effective therapeutic alliance between the patients and caregivers, and enables a more collaborative approach to treatment [10]. This is particularly important because inclusion of the patients as decision makers and stakeholders in their treatment, improves attitudes and practices, self-efficacy and adherence, which are important mediators of improved biomedical and psychosocial outcomes [11].

The efficacy of TPE interventions have been established in several randomized controlled trials [6,12,13]. Although recently published systematic reviews and meta-analysis have estimated their effectiveness, however, these have either been limited to a specific set of TPE interventions or to subsets of patients [12,14,15]. Moreover, none of these have critically reviewed the use of TPE interventions in psychosocial and psychological outcomes or the theoretical underpinning and implementation considerations for these interventions in different settings. Our systematic review and meta-analysis address this gap in knowledge and aim to:

- a. Present a critical synthesis of theoretical basis and development of TPE interventions for obesity and diabetes.
- b. Present quantitative evidence for efficacy of these interventions across a range of biomedical, psychosocial and psychological outcomes.

This review is part of a larger project PARTNERSHIP (Putting the pAtient firSt: maNagemEnt of chRonic diSeases by tHerapeutIc Patient education), leading a series of evidence synthesis studies on the role of therapeutic patient education in the management of chronic disorders.

Materials and Methods

Information Sources & Search Strategy

The present systematic review and meta-analysis (SRMA) builds on our previous large scale SRMA which presented the effectiveness of TPE interventions across all the medical specialties [16]. This SRMA provides a more in-depth review and critical analyses of TPE interventions for obesity and diabetes. The database search for the systematic review was performed in Web of Science, MEDLINE, CINAHL, PsycINFO and COCHRANE database, from inception until August 2019. The search strategy for the original systematic review is presented in Supplementary Table 1.

Eligibility Criteria

For this review, we considered all those studies which presented the effectiveness of TPE interventions in chronic metabolic disorders (tracer disorders obesity and diabetes mellitus) presenting in community or healthcare settings. We considered only randomized and cluster randomized controlled trials conducted among adults ≥ 18 years old. We considered a range of outcomes including but not limited to biological parameters, psychological symptomology, and quality of life indicators. These indicators may include (but not limited to): disease progression, treatment outcome, rate of complications, rate of relapse, hospitalization, self-care, compliance and adherence to treatment, health knowledge, attitudes and behaviors, and quality of life assessed using valid and reliable scales. Only primary outcomes tested at primary time points were included.

Data Extraction

Two reviewers (JC, AW) working independently from one another screened the articles for eligibility and data extraction. Using a pretested data extraction form, we extracted qualitative data pertaining to the interventions which included rationale of interventions, delivery techniques and content of interventions content and density of dose and characteristics of delivery agents. We also extracted data on modalities used for delivery of TPE interventions. Effort was made to map the content and syllabus of each intervention using a framework developed by the review team. The content of the interventions was mapped to five domains: disease management, lifestyle changes, coping skills, disease processes and interpersonal skills.

Meta-analysis

Quantitative data to calculate effect sizes included mean (SD) and sample sizes of intervention and control arms for continuous outcomes and frequency of events and sample sizes for categorical

outcomes. If these data were not available, then we extracted odds ratios, mean differences, and sample sizes [17]. Data were pooled using random effects due to expected methodological and clinical heterogeneity across the studies [17]. Funnel plot was used to assess publication bias in reporting of outcomes, after which Duwall & Tweedie's Trim & Fill method would be used to provide adjusted effect sizes and associated 95% CI [18]. Subgroup analysis with mixed effects and meta-regression analyses were performed to delineate moderators of TPE intervention effects [19].

Risk of bias assessment

Cochrane tool for risk of bias assessment in RCTs was used to assess risk of bias in selection and allocation of study participants to interventions, blinding of outcome assessors, attrition bias and other biases [17][20].

Results

A careful review of 5388 titles and abstracts was performed to identify 984 full texts for eligibility for inclusion in the review. Out of these 984 full texts, we included a 497 in our original database of TPE interventions across all medical specialties. A total of 54 of these RCTs were conducted among patients with obesity and DM and were thus, qualitatively synthesized. Out of these, 47 were included into quantitative synthesis (Figure 1).

Characteristics of interventions

Out of the 54 eligible interventions, 46 (85.19%) were focused on DM, six (11.11%) on obesity and overweight. These interventions were delivered by allied health workers (n= 28), multidisciplinary teams (n= 17), research teams (n= 6), peers and peer leaders (n= 2) and doctors (n= 1). A variety of delivery formats were used including in groups (n= 16), individually (n= 15), electronically (n= 8) and mixed formats (n= 12). These interventions varied in use of delivery techniques with the highest proportion of interventions facilitating supervision (n= 54), interactive presentations (n= 51), practical work (n= 44), use of information media (n= 33), round table discussions (n= 20), brainstorming (n= 14), use of logbooks (n= 11), and animation media (n= 11) among others (Figure 2). Detailed characteristics of included RCTs are presented in supplementary table 2.

Ingredients of interventions

While the most taught components for disease management included managing complications (n= 48) and self-monitoring (n= 41). Information for lifestyle changes spanned across awareness of risk factors (n= 38), implementation of lifestyle changes (n= 45) and prevention of complications (n=49). Several cognitive and behavioral coping skills were also taught in these interventions including self-care (n= 52), situational awareness (n= 45), critical thinking (n= 40), goal setting (n= 35), self-confidence (n= 31), problem solving (n= 18) and stress management (n= 17). Information regarding disease processes

revolved around health behaviors (n= 51) and interpersonal skills were taught in 19 interventions (Figure 3). There were no differences in use of different curriculum content of TPE interventions based on varying delivery formats (Supplementary table 3)

Description of interventions according to delivery format

Electronic interventions: Among these interventions, five were delivered through internet media [21-25] and three using telephones [26-28]. Carter et al., tested an online diabetes self-management intervention for urban African Americans with type 2 DM, to enable them to assume more responsibility for their health and improve DM related outcomes [21]. This intervention was delivered by telehealth nurses who delivered biweekly 30-minute video conferences including modules on self-management, nutrition education, physical activity. It also allowed for social networking among patients. McKay et al., aimed to improve physical activity among DM patients with sedentary lifestyle mediated by occupational therapists. The participants were in goal-setting, received and could post messages to an on-line personal coach, and participated in peer group support areas [22]. Shea et al., tested an intervention based on videoconferencing and remote monitoring of glucose and BP facilitated by project case manager under supervision of diabetologists [25]. Blomfield et al., tested two interventions: i) guided self-help strategies with a website enabled online food and exercise diary with feedbacks provided and ii) in this arm, participants were provided with DVDs, Weight Loss Handbooks, pedometer and lifestyle diary with no feedback. Ramadas et al., utilized a web-based dietary lesson plans personalized according to patients supervised by study nutritionists [24].

Telephone delivered interventions preventing glycemic relapse through routine follow-ups ensuring self-care behaviors [26], adherence to medication using educational modules [28] and automated calls to improve management of DM2 (using Bluetooth enabled glucometer) by improving physical activity, medication taking and nutrition [27].

Group interventions: Interventions were delivered to groups of patients as small as 3 participants [29] and as large as 70 [30]. Seven interventions were delivered by allied health workers including technical health assistants [31,32], educators [33,34], social workers [35], volunteer peers managed by diabetes nurses [36] and psychologists [37].

Kruger et al., employed technical assistants trained by nurses and podiatrists. Participants were provided with lecture videos and foot check sheet, along with usual teaching on footcare and hands-on learning of footcare techniques. Chavepojnkamjorn et al., developed a self-help program facilitated by trained allied health staff who imparted knowledge of DM, skills for dietary control and physical exercise, self-monitoring and motivation for experiences sharing and training skills for group leaders [32]. Trained educators were utilized to facilitate education programs for physicians and people with diabetes where active patient participation and self-care was emphasized to improve DM care [33]. Gillet et al., provided

structured education to newly diagnosed patients with DM to aid in goal setting mainly for weight loss and smoking cessation [34].

Soennichsen et al, delivered modules of patient education on interdisciplinary care where at regular intervals where agreement on therapeutic goals and shared patient-physician decision-making were encouraged [29]. Three of these interventions [35-37] utilized psychotherapeutic skills: problem solving, provision and social and emotional support and self-regulation (dietary and weight management) to improve diabetes and obesity outcomes.

By utilizing multidisciplinary teams, five of the interventions focused on imparting self-care and self-management techniques for DM [7,9,38-40]. Two interventions used psychotherapeutic skills. Trouilloud et al., imparted skills on dietary management, physical activity and medication using educational and problem solving activities [7]. While Whitehead et al., used principles of mindfulness and acceptance training in relation to difficult thoughts and feelings [9]. In other interventions delivered by multidisciplinary teams [38-40], unique strategies included inclusion of family members [38], and training to recognize when BG is too high or low and anticipate when it is likely to rise or fall [39].

Interventions delivered by trained peers [41] and peer leaders [42] focused on educational and self-management aspects of diabetes. While interventions delivered by research teams besides imparting basic education and self-management skills also touched upon more technical points on kinetics of insulin and cues signaling hypoglycemia and management of medicine [30,43].

Individually delivered interventions: There were 16 interventions which aimed to deliver TPE interventions using a personalized and individual approach [5,44-58]. All these interventions were focused on lifestyle and disease education and self-management techniques for diabetes except four interventions which were primarily aimed for smoking cessation among patients with diabetes [46,48]; personalized diabetes risk assessments during ophthalmologic visits [56] and improving physical activity [58].

Six of these interventions employed clinical examinations and assessments to individual patients prior to delivery of TPE intervention [5,45,48,50,52,58]. For instance, Moriyama et al., performed diabetes related clinical examination for individual patients followed by education about diet, exercise, smoking cessation, medication and stress management, prevention of diabetic complications [5]. Nejhaddadgar et al., after performing clinical assessments delivered a program based on the PRECEDE model (knowledge, attitudes, social and family support), to improve self-efficacy [45]. Shubayama et al., performed one to one assessment of eating patterns, physical activity, and self-care for diabetic complications and thereafter, assisted in goal setting and regular evaluation and feedback support [50]. Besides offering educational modules, Seligman et al., provided food packages containing diabetes-appropriate foods and HbA1c testing. Aiello et al, offered an intervention package for ophthalmological care for patients with DM including measurement of HbA1c level, blood pressure, and retinopathy

severity; demonstration of graph showing risk for worsening retinopathy and comparing previous and current HbA1c levels; risk assessment for renal disease and retinopathy [56].

Multimodal interventions: Among these 13 interventions, TPE was provided by pharmacists [13,59-61], nutritionists [62], counselors [63], lifestyle coaches [64], multidisciplinary teams [65-68] and researchers [69,70]. Pharmacists delivered their interventions either using face to face meetings or by telephoning the patients. These interventions were focused on medication counseling but also included preventive education. The pharmacist-led interventions addressed identification and resolution of drug-related problems and adherence to *pill-box* and demonstration of insulin injection technique [59], generalized education on DM and meal planning using food pyramid chart provided by the pharmacists [60], and initial face to face sessions followed by telephone calls [61]. Sonal Sekhar and colleagues also tested effectiveness of clinical pharmacists in providing education of footcare and podiatry reviews [13].

Three interventions tested personalized care for patients with obesity [62-64]. These interventions were personalized according to the patients' needs and had varied goals. Assuncao et al., employed two nutritionists to aid patients in reducing weight and control risk factors of noncommunicable chronic diseases. The intervention recipients received a manual with photographs of portion sizes of prescribed foods, dietetic prescription, guidance on choosing and substituting foods, encouragement to consume vegetables, fruit and low-fat foods; and to perform physical activity and promotion of follow up visits [62]. Perri et al., initiated obesity interventions in underserved rural settings using counselors to encourage sustained weight loss [63]. Wadden et al., tested a 2 year long intervention where lifestyle coaches performed quarterly visits combined with monthly 10 to 15 minutes long sessions followed by telephone delivered counseling every other month in year 2. Besides this, patients also received a pedometer, calorie-counting book, dietary and physical activity goal setting meal replacements or weight-loss medication [64].

TPE interventions delivered by multidisciplinary teams were tested in four interventions [65-68]. These interventions were quite heterogenous. Korhonen et al., delivered the TPE interventions on DM to hospitalized patients with instructions to adjust insulin dose in special situations [65]. Wagner et al., utilized automated telephone self-management and patient activation linked to nurse care by phone [68]. Chao et al., tested an integrated health management model to improve health of older adults with DM in community by ensuring health record establishment, health evaluation and health management [67]. Remaining two interventions were delivered by delivered by researchers [69,70] who tested TPE interventions comprising of structured education for Functional Insulin Treatment [70] and computer assisted intervention providing automated feedback on key barriers to dietary self-management, goal setting and problem-solving counselling [69].

Efficacy of Interventions

Biological outcomes: A total of 38 trials (n = 9879 participants) pertaining to effectiveness of therapeutic patient education interventions were included in meta-analyses. There was substantial heterogeneity in reporting of these outcomes ($I^2= 88.35\%$, $Q= 317.64$), with significant improvement (SMD=0.36, 95% CI: 0.23 to 0.49) noted in biomedical outcomes in the intervention group (Supplementary Figure 1 and Figure 4). Sensitivity analyses did not reveal any changes in significance of results. Funnel plot was slightly asymmetric (Figure 5); however, Egger's regression statistic was statistically non-significant ($t= 1.35$, $P= 0.18$) (figure 5). Allied health workers and multidisciplinary teams and different formats of delivery of these interventions yielded comparable effect sizes in subgroup analyses, while there was insufficient evidence for interventions delivered by doctors, peers, and research staff and through use of electronic media (information and animation media) during the delivery of TPE intervention (Table 2).

Due to heterogeneity pertaining to different outcomes reported in studies, fully random effects analyses were run. These analyses revealed a higher effect size (SMD= 0.463, 95% CI: 0.17 to 0.75) in comparison with the pairwise meta-analyses (Figure 4). It revealed a significant intervention effect for outcomes of body weight (SMD= 0.53; 95% CI: 0.24 to 0.81); eGFR (SMD= 0.78; 95% CI: 0.26 to 1.30); serum glucose (SMD= 1.144; 95% CI: 0.43 to 1.86); and HbA1c (SMD= 0.268; 95% CI: 0.12 to 0.42). However, results for BMI (SMD= 0.36, 95% CI: -0.16 to 0.87) and UKPDS risk (SMD= -0.14 to -0.84 to 0.56) were inconclusive due to imprecise effect sizes owing to a small sample size.

Adherence: Adherence to treatment regimen was reported in two studies, with a cumulative sample size of 521 participants. There was no significant statistical heterogeneity in reporting of this outcome ($I^2= 0\%$, $Q= 0.01$). It yielded a weak and imprecise effect size in favor of the intervention group (SMD= 0.310, 95% CI: 0.05 to 0.57).

Knowledge: Knowledge was reported as a primary outcome in two studies, with a cumulative sample size of 199 participants. The reporting of this outcome was substantially heterogeneous ($I^2= 98.66\%$, $Q= 74.36$). Although the effect size showed improvement in favor of the intervention group, the effect sizes were imprecise and statistically non-significant (SMD= 2.60, 95% CI: -1.44 to 6.64).

Quality of life: Quality of life mental was reported in two studies, with a cumulative sample size of 255 participants. It did not reveal statically significant improvement in favor of the intervention group (SMD= 1.57, 95% CI: -0.54 to 3.68, $I^2= 98.05\%$, $Q= 51.32$). Quality of life physical was reported in only three studies, with a cumulative sample size of 410 participants. There was evidence for high statistical heterogeneity with no evidence of improvement among participants undergoing TPE interventions (SMD= 0.682, 95% CI: -0.16 to 1.52), however, the effect sizes were imprecise.

Risk of bias: Among the included RCTs, risk of bias was low in selective reporting (n= 51), attrition bias (n=38), random sequence generation (n=20), and allocation concealment (n=5) (Figure 6).

Discussion

This systematic review and meta-analysis critically analyzes the experimental literature on TPE interventions for obesity and diabetes. Using piloted taxonomies, we present a synthesis on delivery techniques and modalities adopted by various investigators. Besides this, curriculum and skills covered in each of the intervention has been summarized to aid in future development of TPE interventions. We show that TPE interventions bring about significant improvements in biomedical outcomes among patients with DM and obesity. Only a few of the interventions explored psychological and psychosocial outcomes or mediators of TPE interventions as primary goals.

The present systematic review and meta-analysis demonstrates moderate strength effect sizes in improvement of biomedical outcomes among patients with DM and obesity. It corroborates findings from multiple RCTs and meta-analysis reporting TPE interventions as an essential and effective component of patient care [71-73]. A plethora of literature on TPE indicate these interventions to be a core tenet in building trust and a therapeutic relationship between the physician and the patient [10,74,75]. Besides these, TPE interventions also enable the health professionals to tackle psychosocial aspects of chronic diseases. For instance, people with obesity in addition to their symptoms also demonstrate fear, loneliness and stigma which may mediate food intake and determine future prognosis. The TPE approach tackle these biopsychosocial challenges to achieve holistic health. Recognizing its importance, stakeholders in the field of TPE have long advocated for improving competency of physicians and allied health staff in delivering TPE [10].

The World Health Organization has identified several barriers in implementation of TPE interventions [10] including lack of human resource trained in TPE. Another major obstacle is the nature of medical training which results in a pervasive and mechanical approach to treatment of patients. This approach to medical training is often suitable for acute diseases, but managing chronic diseases require a more holistic approach. There is insufficient teamwork between the physicians, allied health staff and community stakeholders. This resistance to teamwork is often counter-intuitive from an implementation perspective of TPE. There is a lack of commitment from policy makers and institutions who believe in bio-medical approach to medical training. This often translates to lack of educational resources, finances and infrastructure necessary for implementation of TPE interventions on a large scale [10].

The present systematic review revealed that TPE interventions delivered through different media and delivery formats maybe equally effective. Similarly, trained allied health staff may present a more cost-effective solution to establishing a TPE program in hospital and community setting [9,37,50,68,76]. Therefore, these interventions can be tailored to the setting according to availability of human and financial resources. Some of these interventions could be more personalized and involve provision of expensive hardware for self-monitoring and management. This may not be possible in low-resourced

settings. Nonetheless, by recognizing needs of the end-users and acceptability of TPE interventions, these could be tailored.

Another consideration is the multidisciplinary nature of TPE interventions. These interventions may be underpinned by different theories and psychotherapeutic underpinnings [11]. The psychotherapeutic approaches include principles of cognitive and behavioral therapies, learning theories and different definitions and meanings of health literacy. More influential theories include Bandura's social foundations of thought of and action based on social cognition theory and Ajzen's theory of planned behavior [11]. However, we show that where educational and human resources do not allow, simpler programs may also be equally effective. This assertion is corroborated by our meta-regression analyses where use of different curriculum content and techniques do not lead to variation in effect sizes of TPE interventions.

Strengths & Limitations

The present systematic review and meta-analysis is the first concerted effort to synthesize evidence for development and implementation of TPE interventions. Besides these important considerations, efficacy of these interventions in obesity and diabetes have been thoroughly analyzed. However, there are also some weaknesses in the study design. The studies included in this systematic review were identified from a subset of studies from our larger review on 497 TPE interventions across all the specialties. Although all effort was made to identify and include relevant RCTs, there is a chance of missing relevant studies. This weakness is, however, inherent to all systematic reviews. Furthermore, the reviewed TPE interventions were quite heterogeneous, owing to heterogeneous study samples, delivery formats and settings.

Another important limitation is that we only meta-analyzed primary outcomes presented by RCTs included in this review. This was decided by the review team because the studies focused on biomedical outcomes may not have tailored content to improve other secondary outcomes such as quality of life or psychological health of patients. These latter outcomes were presented by only a few numbers of studies. Future studies should consider meta-analysis of both the primary and secondary outcomes in all the studies.

Conclusion

In conclusion, TPE interventions lead to significant improvements across several health indicators among patients with diabetes and obesity. The trials included in this review used heterogeneous delivery techniques, and intervention delivery agents. Use of electronic media such as short messaging services (SMS), website based educational programmes, and animation media can be used to deliver TPE

effectively. Using non-specialist delivery agents and electronic media maybe cost-effective and reduce work burden on physicians. However, it is emphasized that physicians should be trained in biopsychosocial dimension of care for chronic diseases for delivering TPE effectively. Effective TPE is essential in building an effective therapeutic relationship [10,74,75], a precursor to effective healthcare delivery. The formation of this therapeutic bond is possible only when physicians are actively involved in therapeutic education programs. This is also emphasized by the WHO working group, which mentions three core tenets of TPE: a. *to help patients to self-manage their chronic disease* b. *education* should be oriented to the health needs of the population and of the patients* and c. *that “learners should gradually become the architects of their own education* [10].

Supplementary Materials: Following supplementary materials have been uploaded with the manuscript:

Supplementary table 1: Search Strategy adapted for PubMed database

Supplementary table 2: Characteristics of interventions included in the review

Supplementary table 3: Differences in content of interventions according to modes of delivery using Kruskal-Wallis test

Supplementary Figure 1: Forest plot showing effectiveness of therapeutic patient education in metabolic disorders

Author Contributions: JC, AW, AG and ZP conceptualized the study and drafted the protocol for the systematic review and meta-analysis. JC and AW searched the academic databases and identified the eligible trials and extracted the data. AW conducted the meta-analysis and interpreted the results. JC and AW wrote the initial draft of the manuscript. ZP, AG, TSH, KG, and FRJ conducted critical review of the manuscript. All authors approved the final version of the manuscript for submission.

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