Exploring the qualitative research on diabetes self-management in middle-aged population of rural area of Pakistan

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This review article aimed at exploring the qualitative health research in self-management of type 2 diabetes and patient's perceptions and experiences of undertaking physical activity and eating behaviour as part of their diabetes self-management. In addition, the study analyzed how the health issue related to diabetes is viewed and addressed in the community of Pakistan and used the concepts of socio-ecological approach to self-management of type 2 diabetes and explored the factors affecting the self-management practices in that country. The other objective of this review was to examine the role of physical inactivity and obesity in the development of type 2 diabetes and its self-management in middle-aged population living in rural area of Pakistan and to propose a randomized controlled trial and evaluate a lifestyle intervention in the management of type 2 diabetes. This qualitative study would make a unique contribution to public health in the rural area of Pakistan addressing the issues and the ways in which diabetes is managed in that region. This study will help to integrate the skills and choices of individuals in managing the diabetes with the services and support they receive from the social environment of family, friends, organizations and cultures, communities and the governments.

Keywords: Type 2 diabetes, qualitative research, self-management, physical activity, lifestyle intervention, barriers to self-management, randomized controlled trial, Pakistan.

INTRODUCTION

Diabetes mellitus is a pandemic disease and is one of the main threats to human health (Narayan, 2005). In the recent estimate of International Diabetes Foundation (IDF), it was mentioned that worldwide there were 366 million people with diabetes in 2011 and 371 million people with diabetes in 2012, with China (92.3 million), India (63 million) and the United States (24.1 million) leading the way. It was estimated that about 4.8 million people died due to diabetes and also 4 out 5 people with diabetes live in low and middle income countries (IDF, 2003; IDF, 2012; IDF, 2014). Economically, Whiting et al. (2011) reported that more than 471 billion US dollars have been spent on diabetes healthcare globally. Pakistan is one of the developing countries where the health and economic impacts of diabetes have been felt. Whiting et al. (2011) estimated that the prevalence rate of the disease in Pakistan is 7.6 -11% and the prevalence rate in the world is 8.3 %. Type 2 diabetes is also a major public health problem in Pakistan as the middle-aged population in that country is overweight or obese, lack of physical activity, unhealthy food and eating habits exposing this population to a high risk of type 2 diabetes (Ansari, 2009). In the local context, prevalence of type 2 diabetes
in Pakistan for the year 2000 was 7.6 % (5.2 million populations) and for 2030 it will increase to around 15% (13.8 million populations) and as such Pakistan is ranked 7th on diabetes prevalence list (WHO, 2004). It was identified in a survey (Jafar et al., 2006) that on the age-specific prevalence of overweight and obesity, more than 40% of women and 30% of men aged 35–54 years was classified as overweight or obese. Despite the high prevalence of diabetes and serious long term complications, there is still lack of established evidence-based guidelines for self-management (ADA, 2006) and translation of practice recommendations to care in Asian countries (Rayappa et al., 1998) and as well as in developed countries (Chin et al., 2000). This research will address the middle-aged population of Pakistan with diabetes aged between 40-60 years. This is because the highest age-specific prevalence of diabetes in Pakistan and in line with the latest estimates of International Diabetes Federation on the greatest number of people with diabetes is between 40-59 years (Whiting et al., 2011). In addition, keeping in view the high prevalence of diabetes and serious long-term complications, promoting an active lifestyle or regular exercise has become the highest public health priority in Pakistan. In this context, this project is significant in addressing the prevalence and the serious long-term complications associated with type 2 diabetes.

There is a need for self-management approach for patients of type 2 diabetes and the assessment of quality of diabetes care in the community can help draw attention to the need for improving diabetes self-management and provide a benchmark for monitoring changes over time.

**Literature Review**

A literature review was carried out in order to explore the qualitative research in self-management of type 2 diabetes and to identify the socio-ecological approach to self-management of type 2 diabetes. Electronic databases were searched, including Cochrane library, Medline and Embase. References of all retrieved articles were checked for relevant studies. The selection of studies was based on the following criteria:

**Interventions:** educational interventions compared with usual care, physical activity, diet interventions and behavioural intervention.

**Participants:** middle-aged population, aged 40-65 with poorly controlled type 2 diabetes.

**Outcomes:** Studies must report haemoglobin (HbA1c) or hypoglycemia episodes, diabetic complications, cardiovascular disease and quality of life.

**Design:** Studies related to self-management of type 2 diabetes were included. The search key words were type 2 diabetes, Qualitative design, socio-ecological approach and self-management.

The literature survey revealed that diabetes self-management education is the cornerstone of diabetes care (Mensing et al., 2007). There are several studies indicated an association between diabetes self-management and improved diabetes knowledge and self-management behaviours and improved clinical outcomes (Norris et al., 2002). The detailed literature review on self-management of type 2 diabetes on middle-aged population of Pakistan has been provided by Ansari et al. (2014). However, authors of a meta-analysis of diabetes self-management programmes reported sharp declines in benefits within one month post intervention (Norris et al., 2002) suggesting that self-management interventions alone do not enable individuals to maintain behavioural changes.

The improved outcomes were reported when diabetes self-management was carried out for a longer duration, community-based (CDC, 2002), included follow-up support (Norris et al., 2002), and provided culturally sensitive interventions (Norris et al., 2002; Brown, 1999), and addressed psychosocial issues (Rood, 1996; Norris et al., 2002). In addition, the social interaction between the patients and doctors is of great significance. The patients of diabetes need to engage with a range of health professionals. Gaining knowledge of the patient's perspective builds on traditional models of physician-patient communication (Fisher et al., 2005) provides greater clarity to the range of lay understandings that should be explored as a component of effective risk communication.

A framework for integrating the resources and supports for self-management with key components of clinical care was also provided by Wagner et al. (1996) in their chronic care model. A number of studies have also suggested that patient understanding and beliefs about health and illness may be shaped by historical and local contexts (Macfarlane and Kelleher, 2002), whether respondents are thinking about health or behaviour in general or about their own (Blaxter, 1990; French et al., 2001), and personal experience and observation (Davison et al., 1991).

It has been demonstrated in literature that the person is solely responsible to take care of his/her diabetes related problems and its management and therefore the issue of self-management becomes more important for those with chronic disease, where only the patient can be responsible for day to day care over the length of the illness (Lorig and Holman, 2003). It is generally agreed that self-management is required for control of chronic diseases and for prevention of disease complications; however, patients generally do not adhere to self-management recommendations (Sherbourne et al., 1992; Gochman, 1997; Glasgow and Eakin, 2008). The adherence to the recommendations and barriers are both problematic for “lifestyle” behaviour such as eating patterns and physical activity rather than medication adherence (Ansari, 2009; Brown, 1990; Roter et al., 1998). This is evident from the culture, tradition and lifestyle behavior of the people of Pakistan that both the eating patterns and physical activity are posing a great deal of difficulties to middle-aged population with diabetes.
There is compelling evidence that higher levels of social support are related to better long-term self-management and better health outcomes (Kaplan and Toshima, 1990; Uchino et al., 1996). There is also a significant relationship between support and health where support can be accessed from a variety of sources, including spouses, family, friends and neighbours (Dignam et al., 1986). The relationships between support and immunity (Cohen et al., 1997), health status and health behaviours (Glasgow and Toobert, 1998), mortality and quality of life (House et al., 1988; Glasgow et al., 1997) have also been reported in the literature. King et al (2010) has demonstrated that self-efficacy, problem solving, and social environment support are associated with diabetes self-management behaviours.

The health services in the community in Pakistan are not adequate and diabetes health management programme in the community health clinics does not provide enough help and support to the patients. Shortage of community doctors and expensive consultation with private doctors make the life of patients more difficult in terms of managing their diabetes in that region of Pakistan. These clinics in Pakistan face special challenges to provide diabetes care to the poor patients as most of these clinics do not meet the evidence-based quality of care standards as compared to the targets established by the American Diabetes Association (ADA, 2000). Similar cases have been reported in several studies in diversified health care settings; including academic institutions (Peters et al., 1996), health maintenance organization (Miller and Hirsch, 1994), health centers (Chin et al., 2000) and medical providers (Chin et al., 1998) where substantial portion of diabetes care does not meet the evidence-based quality of standard care. Wagner et al. (2001) have reported that community-based health clinics and their patients have fewer resources than the private clinics and the clinics often lack access to integrated delivery system, and their small size limits the financial feasibility of full-time teams devoted solely to diabetes care.

The literature review has provided guidance to identify future areas of research and to explore the socio-ecological approach to self-management of type 2 diabetes and its complications to middle-aged population of Pakistan using qualitative approach. There is only one study conducted in Pakistan on diabetes knowledge, beliefs and practices among people with diabetes (Rafique and Shaikh, 2006). The study provided further evidence that there was a lack of information available to people with diabetes in Pakistan as the large population has never received any diabetes education (Rafique and Shaikh, 2006). This qualitative study would make a unique contribution to public health in the rural area of Pakistan. This will be first type detailed study of diabetes self-management among the population of Pakistan. It will address the issues and the ways in which diabetes is viewed and managed in that region. The study will also be useful for health care professionals suggesting that coping with diagnosis and living with diabetes is affected by a complex constellation of factors, including life circumstances, social support, gender roles and economy.

Aims and Objectives

This qualitative research is divided into three phases:
1. Use of Socio-ecological Approach to self-management of type 2 diabetes
2. Exploring the factors affecting the self-management practices
3. Physical activity and dietary intervention (a proposed randomized controlled trial).

The first phase uses the qualitative health approach conducting one-on-one interviews with a sample of informants – patients of type 2 diabetes (n=30) and explores patients perceptions and experiences of undertaking physical activity and eating behaviour as part of their diabetes self-management.

In the second phase, the study analyzes how the health issue related to diabetes is viewed and addressed in the community and identifies the barriers to diabetes care in community and healthcare clinics. In addition, this study helps to minimize the gap between the physician-patient understanding and management of diabetes. The study then compares the outcome of qualitative research in a diversified population of Pakistan in relation to self-management of type 2 diabetes in that country highlighting the cultural differences and barriers to self-management.

The third phase of study aims at examining the role of physical inactivity and obesity in the development of type 2 diabetes and its self-management in a middle-aged population living in rural area of Pakistan and to evaluate a lifestyle intervention in the management of type 2 diabetes. The intervention aims at conducting a randomized controlled trial to determine whether the intervention of physical activity and diet in comparison with usual medical care lowers hemoglobin (HbA1c) in patients with type 2 diabetes. These types of trials are critical and significant in determining if the culturally tailored interventions are effective in the practical world in which patients live as these patients with diabetes in sub-continent may have different characteristics than those in other western countries due to their eating of different foods and drinking habits.

Research Questions and Hypotheses

The research questions have been formulated as follows:-

1. Will this study help to enhance the patient understanding of self-management of diabetes and will
it minimize the gap between the physician-patient interactions?
2. What factors affect the self-management practices of people with type 2 diabetes in Pakistan?
3. Will hemoglobin (HbA1c) improve after the 90 days trial of lifestyle interventions in patients with poorly controlled type 2 diabetes?
4. Will physical activity and healthy diet lead to reducing the Body Mass Index (BMI) and consequently the risk of diabetes in patients of type 2 diabetes in that region?

Hypotheses: The following hypotheses are to be tested in this study:
1. The lifestyle interventions in patients with poorly controlled diabetes will lead to reduction of 1% hemoglobin (HbA1c) in 90 days trial. (HbA1c as Primary outcome variable)
2. The self-management of type 2 diabetes will reduce 5% weight in patients in 90 days trial and consequently the BMI (BMI as secondary outcome variable).

MATERIALS AND METHODS

Study Design and Sampling Method

The patients will be recruited from the medical centre in rural area of Abbottabad, Pakistan conducting the study of management of type 2 diabetes among the population aged 40-65 years. The eligibility of patients will be subjected to further screening if their records will not be found in the clinic database. The patients with diabetes having HbA1c >7.5% will be included in this study and patients having coexisting liver, kidney or thyroid disorder will be excluded from this study. The Word Health Organization (WHO, 2006) diabetes criteria will be followed in the selection of the patients with diabetes. The study will be conducted in three sequential phases as mentioned above in the section of Aims and objectives.

Phase I: Semi-structured Interviews of patients (n=30)

The study will use qualitative health approach in Phase I conducting one-on-one interview. In phase II, the study will explore factors that affect patient’s self-management and in phase III, a randomized controlled trial will be conducted with physical activity and dietary intervention. A general overview of the study design has been provided in the following Table 1.

Phase II: Exploring the factors affecting the self-management

The aim of Phase II is to explore factors affecting the patient’s self-management activities and addressing the barriers to self-management. In this phase of the study, interviews with type 2 diabetes patients and healthcare providers (General Practitioners) will take place in Pakistan and the data will be analyzed by means of quantitative thematic analysis and guided by the Chronic Care Model as the theoretical framework. The sample size in this study will be guided by the data saturation principle or adapting a pre-defined sample size. The term saturation in the current study means that data becomes repetitive and no new theme can be detected from the participant interviews. This study would utilize the pre-defined sample size. Since the study will be sought to collect in-depth data about factors affecting the type 2 diabetes self-management, it is envisaged that recruiting a small heterogeneous sample from phase I participants would increase the likelihood of discovering a broad range of factors associated with the diabetes self-management.

Phase III: RCT Design – Physical Activity and Dietary Intervention

For the pre-randomized interview, it is expected to invite total 100 patients with type 2 diabetes and as mentioned above only 80 patients will be included in the actual trial based on the inclusion/exclusion criteria. The patients who agree to participate will be required to sign informed consent documents at the clinic where they usually visit for their usual medical care for diabetes. Once the randomization phase is completed, all patients will be instructed to follow-up the usual medical care for their diabetes for the duration of the 90 days trial. In addition, each patient will be asked to go for blood test for HbA1c on day 1 and then return to give blood sample after 90 days.

Those patients randomized to adhere to physical activity and diet (intervention group) will receive education, advice, and behaviour modification skills to help them to maintain a low fat diet, lose weight (goal of 5% weight loss) and moderate intensity physical activity such as brisk walking for 150 minutes/week. All participants will be contacted again after 90 days (3-months) to give their blood sample for HbA1c testing, their weight will be taken and BMI will be calculated. At that time, a questionnaire will be sent via e-mail to participants in intervention group to assess the progress of the physical activity and diet intervention and to control group to assess the progress of the treatment with normal medical care only.

Measurements
The factors which will be measured in this study are the physical activity of participants (an intervention), hemoglobin (HbA1c – primary outcome variable), blood pressure and weight (secondary outcome) whereas the body mass index (BMI) is a calculated variable. The linear regression analysis will be performed after three months between HbA1c and on the blood glucose results to see the reliability of measurement data and to observe any relationship between the two variables.

Physical activity is a key component of lifestyle modification that can help individuals prevent or control
type 2 diabetes. It is considered that diet is probably more important in the initial phases of weight loss, incorporating exercise as part of a weight loss regimen helps maintain weight and prevent weight regain (Klein et al., 2004).

In this study, the message will be given to participants to do 30 minutes of moderate physical activity daily (approximately 8000 step count) and it may offer greater benefits to these patients in managing their diabetes (Wright and Royson, 1996). For measurement of physical activity, the method of step count using pedometer will be used as it has been demonstrated to have a superior validity of step counts over a questionnaire approach in predicting health markers such as BMI and waist circumference (Ewald et al., 2008).

RESULTS AND DISCUSSIONS

Statistical Analysis

The primary outcome will be analysed by an un-paired sample t-test (mean difference between baseline and final HbA1c). The statistical analysis, using STATA software will be carried out on an intention to treat basis and that will subject to the availability of data at follow up (after 90 days) as well as at entry level for individual patients. The linear regression analysis will be performed after three months between HbA1c and on the blood glucose results and it is expected that the HbA1c and the self-glucose monitoring via a glucometer will demonstrate a significant relationship (P < 0.0001) similar to the findings of Nathan et al. (2008) who reported that the linear regression analysis carried out between the HbA1c and blood glucose (BG) values provided the tightest correlations (BG = 28.7 x A1C – 46.7, R2 = 0.84, P< 0.0001), allowing calculation of an estimated average glucose for HbA1C values. The linear regression equations did not differ significantly across subgroups based on age, sex, diabetes type, race/ethnicity, or smoking status.

Data Analysis Method

In this study, the thematic analysis of data will be adopted for analysing the data because the method was developed to meet the needs of investigating the experiences, meanings and the reality of the participants (Brown and Clarke, 2006). The method also allows the study to adopt the element from constructionist notions – to investigate the ways in which events, realities, meanings, experiences are the effects of a range of discourses operating within a society. There are five stages to complete this method – it follows the sequence of familiarization, generating initial codes, searching for themes, reviewing themes, defining and naming and preparing the report.

Ethical Consideration

The scientific validity of the study is a fundamental ethical protection and this study has a scientific merit and clinical value as it aims at using the socio-ecological approach to self-management of type 2 diabetes and will help patients of type 2 diabetes to control their hemoglobin (HbA1c) and help them to understand the importance of physical activity and healthy diet and to enjoy a healthy lifestyle. All the patients will be provided clear instruction about the study.

Table 1. General Overview of the Study Design for the three phases.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Goal</th>
<th>Sample Size</th>
<th>Sampling &amp; Location</th>
<th>Analysis methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>Phase I</td>
<td>Type 2 diabetes patients (semi-structured interview)</td>
<td>n=30 patients</td>
<td>Purposive Medical Centre at AyubMedical college, Pakistan</td>
<td>Qualitative Study</td>
</tr>
<tr>
<td>Phase II</td>
<td>Exploring factors that affect patients’ self-management</td>
<td>20 patients and 5 Health care professionals</td>
<td>Purposive Medical Centre at AyubMedical College, Pakistan</td>
<td>Thematic Analysis</td>
</tr>
<tr>
<td>Phase III</td>
<td>RCT Design – Physical Activity and Dietary Intervention</td>
<td>80 patients will be randomized equally</td>
<td>Medical Centre (Pakistan)</td>
<td>Quantitative Study Statistical Analysis</td>
</tr>
</tbody>
</table>
and informed consent will be obtained and ethical clearance will be taken from a legal authority before conducting this study.

Contribution of the study

This literature review has provided guidance to identify future areas of research and to explore the socio-ecological approach to self-management of type 2 diabetes and its applications to middle-aged population of Pakistan using qualitative approach. This type of study approach is most suitable as it integrates the skills and choices of individuals with the services and support they receive from (a) the social environment of family, friends, organizations and cultures (b) the physical and policy environments of neighbourhoods, communities and governments (Stokols, 1996). The self-management from an ecological perspective requires access to a variety of resources, including services provided by professionals and support for the initiation and maintenance of healthy behaviours (Glasgow, 1995; Glasgow et al., 2000). This qualitative study would make a unique contribution to public health in the rural area of Pakistan addressing the issues and the ways in which diabetes is viewed and managed in that region.

CONCLUSIONS

This study will improve the self-management knowledge and approach to type 2 diabetes among the middle-aged population of Pakistan and enhance the relationship between the medical practitioner and the patients of diabetes. It will also improve the health care system in that country in managing and treating the patients with chronic disease such as diabetes. This study will improve upon the overall functioning of community healthcare clinics to diabetes care in terms of recognizing the symptoms of diabetes to early detection and diagnosis, easy access to community doctors. It has been demonstrated in this study that the level of HbA1c (primary outcome) will reduce by 1% in the patients of poorly controlled type 2 diabetes after the 90 days trial of physical activity and dietary interventions and hence will support the hypothesis and the research questions.

Conflict of Interest

There is no conflict of interest

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http://www.idf.org/home/index.cfm


