Self-Management of Type 2 Diabetes in Middle-Aged Population of Pakistan and Saudi Arabia

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Abstract

This research protocol design is 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 would analyze how the health issue related to diabetes is viewed and addressed in the community (Pakistan and Saudi Arabia) and would use the concepts of socio-ecological approach to self-management of Type 2 diabetes and explore the factors affecting the self-management practices in these countries. The other objective of this protocol is 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 evaluate a lifestyle intervention (Physical Activity and Diet) in the management of Type 2 diabetes. The brief review conducted in this protocol design will identify the potential areas of health care which need attention including 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. This review will impress upon the need to recognize that in developing strategies and interventions to address diabetes, self-care, family support, community education and community ownership are important and it will be demonstrated by the comparison of two culturally diversified populations of Pakistan and Saudi Arabia in relation to the self-management of Type 2 diabetes.

Keywords

Type 2 Diabetes, Self-Management, Hemoglobin (HbA1c), Physical Activity, Diet, Lifestyle Intervention

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1. Introduction

Diabetes mellitus is a pandemic disease and is one of the main threats to human health [1]. In 2003, 194 million people worldwide, ranging in age from 20 to 79 years, had diabetes. It is projected that this number will increase by 72% to 333 million by 2025, and nearly 80% of these cases will be in the poorer industrialized countries [2][3].

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 and 4.8 million people died due to diabetes and also 4 out of 5 people with diabetes live in low and middle income countries [4].

The greatest number of people with diabetes is between 40 to 59 years of age and diabetes caused more than 471 billion dollars to spend on healthcare globally. Figure 1 shows the top three countries in the world for people with diabetes aged 20 - 79 years. It shows a significant increase in diabetic population in these countries from 1995 to 2012. The prevalence of diabetes in the world is 8.3%, in Saudi Arabia, it is 23.4%, in Pakistan, it is 7.89% and in Australia the prevalence of diabetes has reached 9.55% [4]. Figure 2 presents the global projection for the diabetes epidemic from 2011-2030.

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 [5]. 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 [6]. It was found by [7] that on the age-specific prevalence of overweight and obesity, more than 40% of women and 30% of men aged 35 - 54 years were classified as overweight or obese.

In the Kingdom of Saudi Arabia (KSA), the rise in the prevalence of Type 2 diabetes started to gain the attention years after rapid industrialization which took place in the country [8]. Studies carried out since the late 1980’s have shown an increasing trend among adult Saudis [9]-[11]. One of the studies conducted in a large cohort of patients participated from 1995 to 2000, revealed that one of every 5 adults Saudis had Type 2 diabetes [12]. The same cohort showed an alarming prevalence of obesity at 40%, hypertension at 30% and coronary artery disease at 6.2% [13].

Despite the high prevalence of diabetes and serious long term complications, there is still a lack of established evidence-based guidelines for self-management [14] and translation of practice recommendations to care in Asian countries [15] and as well as in developed countries [16]. Therefore, promoting an active lifestyle or regular exercise has become the highest public health priority in both the countries to overcome the onslaught of Type 2 diabetes and in this context this project is very significant as it addresses this important problem of 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.

2. Literature Review

A review of the literature was carried out exploring 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, 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 and diet interventions, behavioural intervention.
- **Participants**: middle-aged population, aged 40 - 60 with poorly controlled Type 2 diabetes.
- **Outcomes**: Studies must report haemoglobin (HbA1c) or hypoglycemia episodes, diabetic complications, cardiovascular disease and quality of life.
- **Design**: The studies related to self-management of Type 2 diabetes were included. The search key words were Type 2 diabetes, socio-ecological approach and self-management.

The literature survey revealed that diabetes self-management education is the cornerstone of diabetes care [17]. There are several studies indicated an association between diabetes self-management and improved diabetes knowledge and self-management behaviours and improved clinical outcomes [18][19]. However, authors of
a meta-analysis of diabetes self-management programmes reported sharp declines in benefits within one month post intervention [18] suggesting that self-management interventions alone do not enable individuals to maintain behaviours changes.

The improved outcomes were reported when diabetes self-management was carried out for a longer duration, community-based [20], included follow-up support [18], and provided culturally sensitive interventions [18] [21], and addressed psychosocial issues [18] [22].

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 [23] provides greater clarity to the range of lay understandings that should be explored as a component of effective risk communication.

Fisher et al. [24] suggested that the quality clinical care and self management are compatible and dependent on each other and without sound care, individual’s efforts may be misdirected and expert clinical care will fall far short of its potential, through patient failure to use prescribed medications to control his blood sugar or to implement its management plans [24].

A framework for integrating the resources and supports for self-management with key components of clinical care was also provided by [25] 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 [26], whether respondents are thinking about health or behaviour in general or about their own [27] [28], and personal experience and observation [29]. The following Figure 1 provides a conceptual framework of self-management of Type 2 diabetes using the socio-ecological approach.

It has been demonstrated in literature that the person is solely responsible to take care of his 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 [30]. 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 [31]-[33].

Adherence to the recommendations and barriers are both problematic for “lifestyle” behaviour such as eating patterns and physical activity rather than medication adherence [5] [34] [35]. This is evident from the culture, tradition and life style 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 [36] [37]. There is also a significant relationship between support and health where support can be assessed from a variety of sources, including spouses, family, friends and neighbours [38]. The relationships between support and immunity [39], health status and health behaviours [40], mortality and quality of life [41] [42] have also been reported in the literature. King et al. [43] 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 [44]. Similar cases have been reported in several studies in diversified health care settings; including academic institutions [45], health maintenance organization [46], health centers [16] and medical providers [47] where substantial portion of diabetes care does not meet the evidence-based quality of standard care. Marshall et al. [48] 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.

In Saudi Arabia, diabetes care is mostly integrated into the public health system through primary health care. Usually, people with diabetes are referred from primary health-care centers to specialist diabetes centers. There are two reasons for this approach. The first reason is that the health care interventions to manage diabetes cases starts with the registration of the patient in a primary health care center and the issuing of diabetes card. Medical diagnosis includes a physical examination and laboratory studies.

In addition to medical treatment, management includes patient education using the diabetes patient’s education guidelines. The aim of these steps is to diagnose diabetes and prevent complications. The second reason is that, when diabetes complications occur, the role of diabetes centre is to manage as well as refer patients to specialist care, such as those in cardiology or surgical departments. In addition, people with diabetes are referred for annual medical examination.
In Saudi Arabia, although the health services are provided on a large scale across the country, diabetes services may need further development and coordination in order to facilitate and improve diabetes care outcomes, especially in the event of the anticipated increase in incidence. Initial exploration of the current diabetes situation in Saudi Arabia indicates that international standards and recommendations are not implemented in every aspect of diabetes care. Moreover, if the current diabetes health-care interventions and self-management approaches are not adequate, it is very likely that the new health care plan in future will fall well short of the goal of providing sustainable national diabetes health care services in the future.

This literature review has provided guidance to identify future areas of research and the main objective is to carry out research work exploring 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 1) the social environment of family, friends, organizations and cultures 2) the physical and policy environments of neighbourhoods, communities and governments [49]. 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 [50] [51].

There is only one study conducted in Pakistan on diabetes knowledge, beliefs and practices among people with diabetes [52]. 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 at all [52]. Also, the study was conducted in an urban university hospital, where diabetes education may be more readily available as compared to rural areas where people have less access to information and will have even poorer diabetes perception and practices.

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. In the context of Saudi Arabia, although the Government injects millions of dollars annually to improve chronic disease health-care services, the absence of community partnerships works against development of ecological resources.

3. Aims and Objectives

This qualitative research has been divided into three phases:

1) Use of Socio-ecological Approach to self-management of Type 2 diabetes;
2) Exploring the factors affecting self-management practices—barriers to self-management;
3) Physical Activity and Dietary Intervention;

The first phase is to use the qualitative health approach conducting one-on-one interviews with a sample of informants—patients of Type 2 diabetes (n = 210) and to explore patients perceptions and experiences of undertaking physical activity and eating behaviour as part of their diabetes self-management. Using semi-structured interviews, qualitative data will be collected and the data will be analyzed by means of thematic analysis using the chronic care model as the conceptual framework.

The second phase, the study would analyze how the health issue related to diabetes is viewed and addressed in the community and identify the barriers to diabetes care in community and healthcare clinics. In addition, this study will help to minimize the gap between the physician-patient understanding and management of diabetes. The study will then compare the outcome of qualitative research from Pakistan with a diversified population of Saudi Arabia 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 this study will aim 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 (Physical Activity and Diet) in the management of Type 2 diabetes. The research protocol design will be developed and implemented addressing the lifestyle interventions for lowering hemoglobin (HbA1c).

In this randomized controlled trial, it will be determined whether the intervention of physical activity and diet in combination of usual medical care lowers 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.

This study will contribute to improving the quality health care for diabetes in health clinics in that region and would recommend a multifactorial approach emphasizing patient education, improved training in behavioural change for providers, and enhanced delivery system [16]. This study will impress upon the need to recognize that in developing strategies and interventions to address diabetes, self-care, family support, community education and community ownership are important [53] [54].

4. Research Questions

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 (related to Phase 1)?

2) What factors affect the self-management practices of people with Type 2 diabetes in Pakistan and Saudi Arabia-Barriers to self-management (related to Phase 2).

3) Will hemoglobin (HbA1c) improve after the 90 days trial of lifestyle interventions in patients with poorly controlled Type 2 diabetes (related to Phase 3)?

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 (Phase 3)?

5. Hypotheses

The following hypotheses are to be tested in this study:

1) The lifestyle interventions (physical activity and diet) 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).

6. Study Design and Sampling Method

The patients will be recruited from the diabetic medical centre in rural area of Peshawar conducting the study of management of Type 2 diabetes among the population aged 30 - 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 > 7.0% will be included in this study and patients having coexisting liver, kidney or thyroid disorder will be excluded from this study. The World Health Organization [55] 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.

7. Phase I Semi-Structured Interviews of Patients (n = 210)

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.

8. 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 will address 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 Saudi Arabia and the data will be analysed 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
Table 1. General overview of the study design.

<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>Measuring self-Management Activities of Type 2 Diabetes Patients (Semi-Structured Interview)</td>
<td>210 Patients Will Be Included</td>
<td>Diabetic Centre at Ayub Medical College, Pakistan</td>
<td>Descriptive Analysis, Categorization of Self-Care Activity Standard Regression Analysis</td>
</tr>
<tr>
<td>Phase II</td>
<td>Exploring Factors That Affect Patients’ Self-Management-Barriers to Self-Management</td>
<td>20 Patients and 10 Health Care Professionals</td>
<td>Diabetic Centre at Ayub Medical College</td>
<td>Thematic Quantitative Content Analysis Comparing with the Saudi Arabian Culture.</td>
</tr>
<tr>
<td>Phase III</td>
<td>RCT Design-Physical Activity and Dietary Intervention</td>
<td>210 Patients Will Be Randomized Equally</td>
<td>Diabetic Centre at Ayub Medical College</td>
<td>Statistical Analysis Using STATA</td>
</tr>
</tbody>
</table>

that recruiting a small heterogeneous sample from phase I (n = 210) participants would increase the likelihood of discovering a broad range of factors associated with the diabetes self-management.

9. Phase III RCT Design—Physical Activity and Dietary Intervention

Study Population and Randomization

Initially 325 patients with Type 2 diabetes will be invited to pre-randomized interview, out of which only 210 patients will be included in the actual trial. For the purpose of this trial, it is expected that out of the 325 patients, 93 patients will not meet the inclusion criteria and 22 patients might refuse to participate in the trial. In that case, two hundred and ten (210) patients will agree to participate and will be required to sign informed consent documents at the clinic where they usually visit for their usual medical care for diabetes.

Therefore, 105 patients will be randomized to intervention group (Physical Activity and Diet) and 105 to the control group (usual medical care). Figure 2 shows their progress during the randomized controlled trial. This RCT trial will not be double-blinded as the participants receiving the education on lifestyle modifications in the community and healthcare clinics would know that they are on the active intervention.

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. The patients will not be allowed to adjust their usual medications and follow their previous prescriptions recommended by their doctors. 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. In addition, participants will be advised not to take any other new treatments for the management of Type 2 diabetes during the trial periods.

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. Those patients randomized to usual medical care (control group) will be instructed to take their normal medicines and follow-up with their doctor as per their normal schedule.

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.

10. Measurement

While Table 1 provides some details on measurements in all three phases of the project, the other specific 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 [56]. 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 [57].

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 [58]. The participants will be given pedometer for a week for the measurement of physical activities (step counts). These participants will be instructed to wear the pedometer on a waist belt, either side and wear it from the early morning till they go to bed in the night. The participants will record the start and end time for each day wearing the pedometer and in the evening record the step count showing on the display without resetting the counter. The participants will return a 7-day diary with a record of all the events. Table 2 shows the baseline characteristics of participants in intervention and control group (Ref: data from the medical records).

### Table 2. Baseline characteristics of intervention and control groups in RCT trial (ref: Medical Record).

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Intervention Group (n = 105)</th>
<th>Control Group (n = 105)</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Years)</td>
<td>Mean (62.5) ± SD (10.5)</td>
<td>Mean (59.5) ± SD (8.5)</td>
<td>0.78</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>55% (n = 58)</td>
<td>58% (n = 61)</td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>45% (n = 47)</td>
<td>42% (n = 44)</td>
<td></td>
</tr>
<tr>
<td>Body Mass Index (Kg/m²)</td>
<td>Mean (30.8) ± SD (6.5)</td>
<td>Mean (30.6) ± SD (6.5)</td>
<td>0.40</td>
</tr>
<tr>
<td>Physical Activity (expected)</td>
<td>95% (8000 Steps)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Adherence to Diet (expected)</td>
<td>98% (n = 103)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td></td>
<td>2% (n = 2)</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Baseline Hemoglobin (HbA1c) %</td>
<td>Mean (8.5) ± SD (1.6)</td>
<td>Mean (8.4) ± SD (1.5)</td>
<td>0.59</td>
</tr>
<tr>
<td>Diabetes Medications</td>
<td>Mean (1.75) ± SD (0.8)</td>
<td>Mean (1.82) ± SD (0.8)</td>
<td>0.15</td>
</tr>
</tbody>
</table>

### 11. Method of Analysis

#### 11.1. 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 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. [59] who reported that the linear regression analysis carried out between the HbA1c and blood glucose (BG) values provided the tightest correlations \( BG = 28.7 \times A1C − 46.7, R^2 = 0.84, P < 0.0001 \), 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.

#### 11.2. 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 [60]. 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.

#### 11.3. Sample Size Estimation

The study sample size was determined based on the assumption of the estimation of Standard Deviation (SD).
Therefore, the study design was selected to detect an effect size of 0.5 SD lowering of HbA1c. It was assumed that 10% patients might be lost to follow-up in control group over the period of three months and only 5% patients will be lost to follow-up in intervention group. This assumption was based on impact of education and advice on lifestyle behavioural modifications to patients and overall popularity of this approach among the diabetic patients in sub-continent to manage their glycemic control.

Taking into consideration all these factors, the following parameters were considered: \( \alpha \) = Level of significance test = 0.05, Power = 0.8, \( m \) = the follow-up period 90 days (3 months), Standard Deviation (SD) = 0.5, the sample size was calculated for each group to detect an effect size of 0.5 SD. The sample size (N) for each group was = 105; therefore, the total, \( n = 210 \) patients were recruited to participate in both the groups.

12. Clinical Settings in Pakistan and Saudi Arabia
Diabetic Medical Center, Ayub Medical College, Abbottabad-Pakistan.
- Patients = patients of Type 2 diabetes visiting the medical center.
- Doctors = doctors working in medical center.
Dallah Hospital, Riyadh, Saudi Arabia.

13. 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 diabetic patients 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 and informed consent will be obtained and ethical clearance will be taken from a legal authority before conducting this study.

Finally, the main contribution of this trial is to provide health professionals (diabetes care providers) and patients with Type 2 diabetes an insight into the ways in which diabetes is viewed and managed in that region of Pakistan which will help them in the self-management and treatment of Type 2 diabetes.

14. Conclusions
This study will improve the self-management knowledge and approach to Type 2 diabetes among the middle-aged population of both the countries and enhance the relationship between the medical practitioner and the patients of diabetes. It will also improve the health care system in these countries 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 question.

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