

Abstract

Knee osteoarthritis (OA) is a degenerative and weight bearing joint disease that resulted from wear and tear of articular cartilage. It is more common in the overweight and obese knee OA patients. The objectives of pilot study were to assess the feasibility, acceptability and challenges of study design, study setting and tools of lower limb rehabilitation protocol among the knee OA patients who are overweight and obese. Twelve overweight and obese knee OA patients attending a Teaching Bay in the Pakistan were enrolled in the study and completed 6 training sessions over 2 weeks. The participants were divided randomly into Intervention Group with Mobile Health (IGW-mH), Intervention Group without Mobile Health (IGWO-mH) and the Control Group (CG). Both intervention groups were provided fifteen days of lower limb rehabilitation protocol but the CG did not. Two text messages per day for three days a week were sent to IGW-mH as a reminder to carry on their training session and instructions of daily care. All participants of intervention groups showed willingness to randomization and adherence to training sessions. The results indicated that eligibility criteria, recruitment rate and randomization procedures were feasible and there were no adverse events from training sessions. The participants demanded Urdu translation and pictures of lower limb rehabilitation protocol.

Key words: *mobile health technology, overweight, knee, osteoarthritis,*

1 Introduction

The most common form of arthritis is osteoarthritis (OA). It is characterized by a progressive destruction of articular cartilage, resulting in severe pain and disability (1). OA has been described as a condition characterized by use-related joint pain experienced on most days in any given month, for which no other cause is apparent (2). The wear and tear of articular cartilage in the knee OA disease is not only the main cause, but it is also considered a disorder of physiological processes that is manifested by progressive lesions of articular cartilage and other structures (3). Worldwide 250 million people, both men and women, are affected with symptomatic knee injury (4). Obesity is a significant as well as rapidly increasing global health issue. More than 39% and 13% of adults were considered overweight (body mass index $> 25 \text{ kg/m}^2$) and obese (body mass index $> 30 \text{ kg/m}^2$) respectively in 2014, and the prevalence of overweight and obesity has doubled

globally since 1980 (5). A recent published research study concluded that the excess of weight and adiposity had a negative impact in increasing pain perception of patients with OA (6). There is a gap in literature for utilizing mHealth to increase the effectiveness of OA self-management intervention delivery (7, 8). Health related services via a mobile device are known as mHealth (9). There is need of mHealth especially for the overweight or obese knee OA patients in order to reduce weight and enhance the quality of life. The objectives of pilot study were to assess the feasibility, acceptability and challenges of study design, study setting and tools of lower limb rehabilitation protocol among the knee OA patients who are overweight and obese. In the current pilot study the training sessions of lower limb rehabilitation protocol were performed in sitting or lying positions without putting mechanical pressure at the knee.

2 Methodology

2.1 Participants

The Participants were recruited via word of mouth by contacting with political and welfare organizations. A published research article suggested that active recruitment strategies were 66.5 times more effective and personal compared to passive recruitment strategies (10). Participants were recruited from the urban area of Punjab, Lahore. Inclusion criteria were both males and females overweight and obese knee OA patients, age between 45 and 60 years, having OA of one or both knees and fulfilling the second mild and three moderate grade criteria of Kellgren and Lawrence Scale (KLS). Grade 0, 1 and 4 of KLS were not included in the pilot study. Exclusion criteria were one or more of the identified flat feet, spinal deformities, knee surgery, corticosteroid injection at the knee, spinal deformities, cardiac problem or hormonal problem. The study was approved by the ethical committee of Rehmatul-Lil-Alameen Postgraduate Institute of Cardiology with reference No. RAIC PESSI/Esst/2019/487, and all participants provided written informed consent before participation in the study.

2.2 Study design

It was a single blinded randomized controlled study design. The participants were unaware about the intervention in the pilot study and therefore it was a single blinded randomized controlled study design. In randomization each participant has an equal chance of selection. Randomization was done by a computer generated number.

2.3 Study population

Study population were overweight and obese knee OA patients from the urban area of District, Lahore, Punjab, Pakistan. Normal weight participants were not included in the pilot study.

2.4 Study randomization

The researcher randomized the 12 participants equally into three groups, intervention group with mobile health (IGW-mH), intervention group without mobile health (IGWO-mH) and the control group (CG). Instructions of daily care were provided to all three groups.

2.5 Measurements and groups protocol

All participants completed baseline measurements of pain, body mass index, mobility, quality of life, activities of daily living, functional capacity,

functional strength, patient satisfaction, exercise adherence and self-management.

After baseline measurements, participants were randomly allocated into three groups by a computer generated number. Participants in two intervention groups were asked to complete six sessions over 2 weeks with their training sessions at their homes. Two weeks rehabilitation protocol was carried out three times a week for two weeks. It was consisted of warming up of 10 minutes followed by lower limb rehabilitation exercises in sitting or lying position. The resistance was provided with the help of elastic bands, force of gravity and ankle weights. At the end of training sessions a cooling down of 10 minutes was performed (table 1).

Table 1. Two weeks rehabilitation protocol

Muscle Group	Frequency	Duration
Hip flexors and extensors	Three times a week	Two weeks
Hip abductors and adductors		
Knee flexors and extensors		
Ankle dorsiflexors, plantarflexors		
Ankle invertors and evertors		
10 minutes warm up at the start and 10 minutes cooling down at the end of each training session.		

Both intervention groups (IGW-mH and IGWO-mH) followed the lower limb rehabilitation protocol and instructions of daily care for two weeks. Two text messages per day for three times a week for two weeks with the help of mHealth were provided only to IGW-mH as a reminder to carry on two week exercise protocol and instructions of daily care. The instructions of daily care are shown in table 2. The control group did not get text messages as a reminder. The CG only followed the instructions of daily care (Table 2).

After completion of the two week exercise protocol, the measurements of pain, body mass index, mobility, quality of life, activities of daily living, functional capacity, functional strength, patient satisfaction, exercise adherence and self management were again retested. These measurements were taken as a testing purpose and were not analyzed.

2.6 Feasibility, acceptability and challenges of study

The feasibility of the study was assessed by eligibility criteria, recruitment rate, dropout (lost to follow up) rate, willingness to the randomised and adverse events of pilot study. The acceptability of study was assessed by patient satisfaction and exercise adherence. The participants demanded the need of Urdu translation and pictures of lower limb rehabilitation protocol in their interviews. The interviews were conducted by the researcher.

Table 2. Instructions of daily care

Activity Name	Explanation
Sitting	Always prefers to sitting than standing.
Walking	Always walk with a stick.
Stair climbing	Avoid stair climbing.
Exercise	Do not walk, jog or run as an exercise plan.
Exercise positions	Always exercise in non-weight bearing positions. e.g sitting or lying positions
Body weight	Reduce your weight by avoiding taking of drinks and fat foods

The participants were also interviewed of future need in the real study. The questions regarding feasibility, acceptability and challenges are shown in table 3.

3 Results and Discussion

Recruitment began and completed in July, 2019. Fourteen participants were selected from the urban area of District, Lahore, Pakistan and assessed for enrollment in the Teaching Bay of Rehmatul-Lil-Alameen Postgraduate Institute of Cardiology. Two participants were excluded, one due to normal weight and the remaining one due to the cardiac problem. Twelve were randomized and completed the pilot study. Enrollment, allocation, follow-up and analysis of pilot study are shown in the flow chart of study (Figure 1).

Eight participants of intervention groups completed six training sessions in two weeks and followed the instructions of daily care, while four participants of

the CG followed the instructions of daily care. All participants showed willingness to randomization. An adverse event, withdrawal or dropout rate was zero. All participants of intervention groups showed exercise adherence to training sessions. All participants of intervention groups showed satisfaction with the rehabilitation protocol.

Table 3. Feasibility, acceptability and challenges of pilot study

Investigations	Questions	Answers
Feasibility	Good eligibility criteria	Yes or No
	Good Recruitment rate	Yes or No
	Dropout (lost to follow up) rate present	Yes or No
	Willingness to the randomised	Yes or No
	Adverse events present	Yes or No
Acceptability	Are you satisfied with the pilot study?	Yes or No
	Are you satisfied with exercise adherence?	Yes or No
Challenges	Do you need Urdu translation of lower limb rehabilitation protocol?	Yes or No
	Do you need pictures of lower limb rehabilitation protocol?	Yes or No
	Do you feel to recommend any future need in real study?	Yes or No

As shown in Figure 2, Researcher identified that the majority participants of intervention groups had following three challenges. These challenges were identified through the interview of participants. The participants demanded Urdu translation and pictures of two weeks lower limb rehabilitation protocol. The participants also demanded the support of the family member for the completion of their rehabilitation protocol. The results of pilot study identified that the participants of IGW-mH resulted more satisfaction and exercise adherence to the lower limb rehabilitation protocol than IGWO-mH and CG.

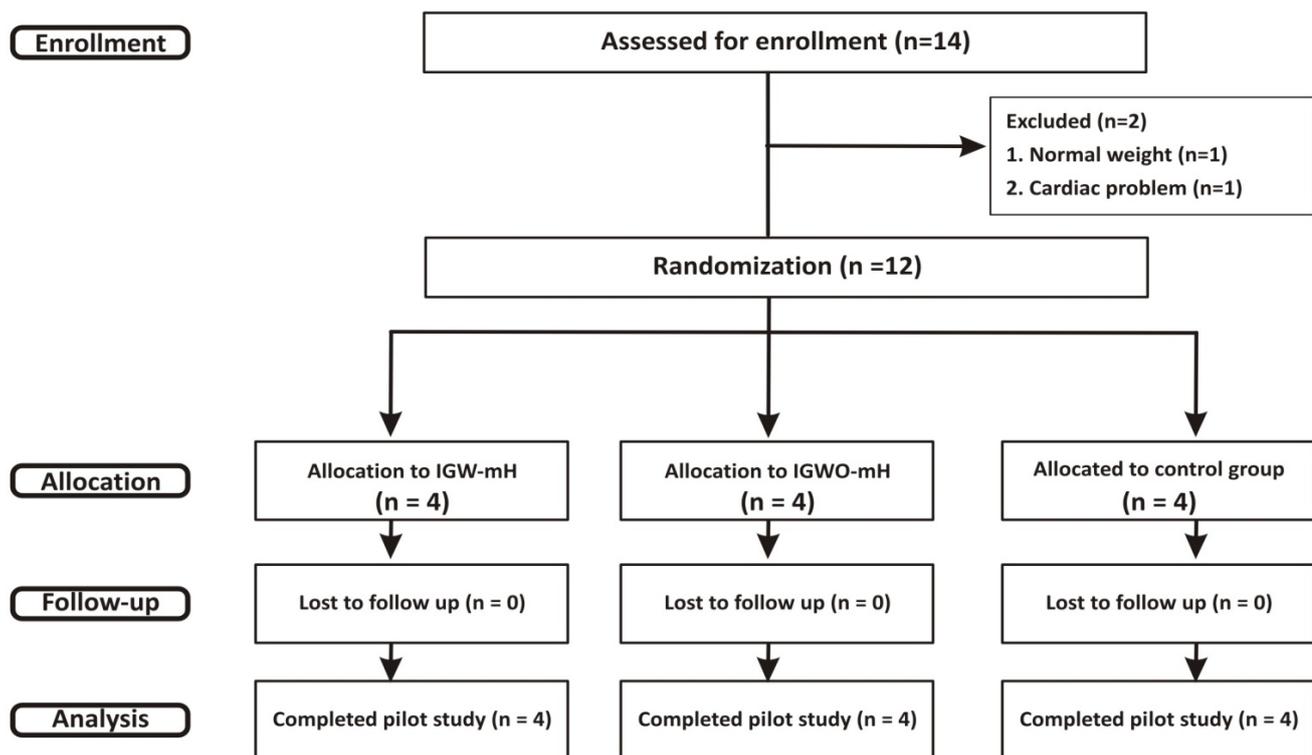


Fig. 1. Flow chart of pilot study

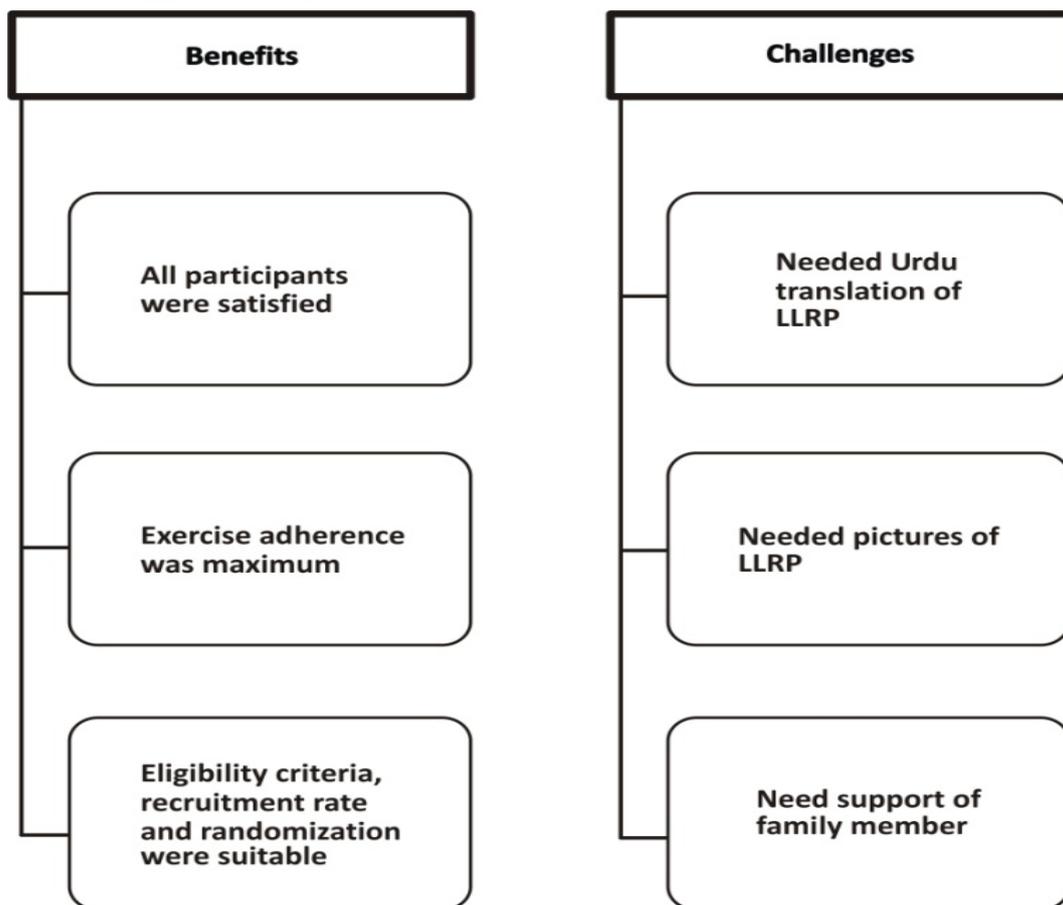


Fig. 2. Output from participant interview

4 Conclusion

The objectives of pilot study were to assess the feasibility, acceptability and challenges of study design, study setting and tools of lower limb rehabilitation protocol among the knee OA patients who are overweight and obese. The results indicated that eligibility criteria, recruitment rate and randomization procedures were feasible and there were no adverse events from training sessions. The participants demanded not only the translated version of lower limb rehabilitation protocol into Urdu language but also in the forms of pictures. However, the aims, methodology and results of current study would require a future trial of long duration to see the effectiveness of rehabilitation protocol using mHealth among the overweight and obese knee OA patients.

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