STUDY PROTOCOL

Smart Phone Applications in the Conservative management of Shoulder dislocation (SPACS): A

multi-center RCT in the efficacy of smart phone applications as an adjunct in the rehabilitation of shoulder dislocations

Abstract

Background:The Glenohumeral joint is the most commonly dislocated joint in the human body as it sacrifices stability for a greater range of motion making it inherently unstable [1,2]. The ongoing instability and subsequent re-dislocation associated with 80-90% of these injuries causes significant long term morbidity for the patient and therefore greater demand on public health resources [1,3,4,5,6]. Recent studies have shown that these complications can be drastically reduced to levels as low as 17% with intensive, regular and ongoing rehabilitation, strengthening and prevention exercises [3,4]. However, these intensive programs are not readily available to the community due to financial contraints and limited access[10,11]. The SPACS trial looks to investigate the efficacy of a smart phone app designed to act as an adjunct to current therapy and improve compliance. Therefore our objective is to examine the efficacy of using an encouraging and educational smart phone application as an adjunct to standard, conservative shoulder rehabilitation programs post shoulder dislocation.

Method/Design: This study is a multi-centre, open-label randomised control trial, with eighteen months follow-up. Patients aged between 15 and 60 years old, that have sustained a shoulder dislocation within the previous week and are to be conservatively managed, capable of participating in a rehabilitation program and have access to a smart phone would be eligible for inclusion in the study. Participating patients will be randomised into two study arms, intervention and control, with both arms receiving the usual access to public and/or private rehabilitation at their discretion. The intervention arm will also have access to the application's information, instructional videos, standardised 12-16 week rehabilitation program and thrice weekly reminders to complete their rehabilitation. The control arm will not have access to the application's content or reminders to complete their therapy. The primary outcome for this study will be the Oxford Shoulder Instability Score (OSIS) over 12 -18 months. The secondary outcome will be progression to surgical intervention due to poor response to conservative management. The OSIS will be pushed to the participants via the mobile application at 0, 3, 6, 12, 24, 52 and 73 weeks from date of injury.

Discussion:The conservative management of shoulder dislocations is difficult for the orthopaedic surgeon with factors such as poor compliance and access to rehabilitation being some of the most significant causes of re-dislocations and long-term instability [1,3,4,5,6]. A proven, evidence based and easily accessible adjunct to current rehabilitation regimes such as a smart phone application would offer a cost effective, pragmatic solution to improve patient outcomes and reduce the strain on health resources.

Background

The glenohumeral joint sacrifices stability for a greater range of motion with only 26% of the humeral head being in contact with the glenoid at any one time. This makes the joint inherently unstable and hence the most commonly dislocated joint of the human body [1]. Primary glenohumeral dislocations are associated with ongoing instability and subsequent re-dislocation in up to 80-90% of cases causing significant long term morbidity for the patient and demand on public health resources [1,3,4,5,6]. Recent studies have shown that these complications can be drastically reduced to levels as low as 17% with intensive, regular and ongoing reh-abilitation, strengthening and prevention exercises [3,4]. Such an intensive program is not realistic for the general public when considering time, geographical and financial constraints [10,11]. However, the recent rise in popularity and availability of smart phones and their associated applications may offer an effective supplement to this gap helping to improve quality of life and reduce demand of public health resources. There are many applications currently available on the market however they all lack regulation and evidence as to their efficacy [4].

The SPACS trial looks to investigate the efficacy of a smart phone app designed to educate patients of appropriate rehabilitation therapy in the conservative management of their shoulder dislocation. We hypothesise that with easily accessible, relevant resources regarding their injury, rehabilitation and prognosis and regular reminders to complete their therapy we will see an improvement in shoulder stability compared to the control arm. The impact of this intervention will be assessed by a significant difference in Oxford Shoulder Instability Scores when comparing the two trial arms.

Study Objectives

Primary Objective:

To analyse the efficacy of a smart phone application as an adjunct to standard, conservative rehabilitation of orthopaedic patients recovering from shoulder dislocations. This will be defined as a clinically and statitically significant improvement in patients OSIS score.

Secondary Objectives:

A) Identify the rate of surgical intervention following failure of conservative management in both the intervention and control arm.

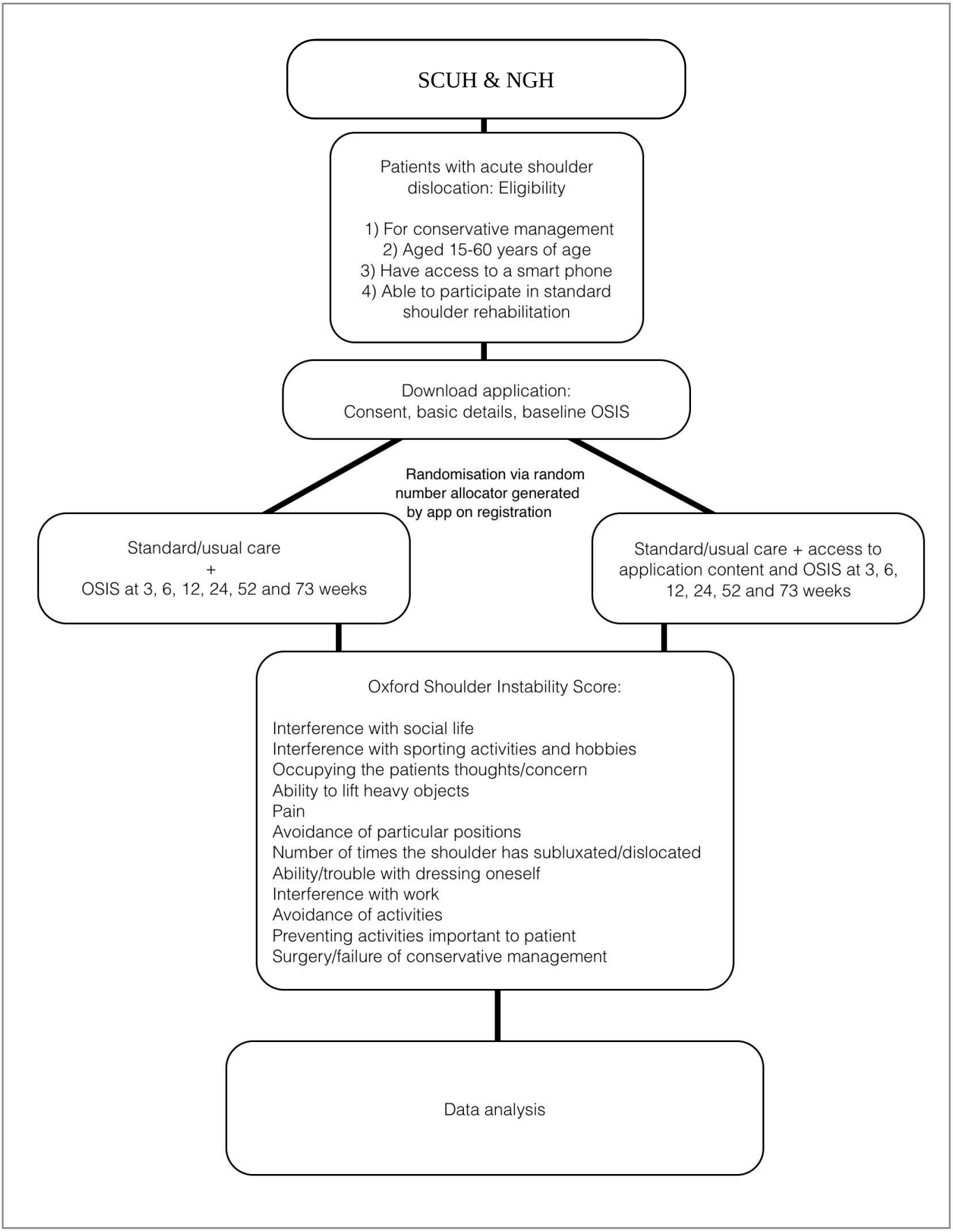
B) Examine the level of compliance to rehabilitation within the intervention and control arms.

Methods/Design

The SPACS study is a multi-centre, open label randomized controlled tiral with an eighteen month follow-up. Please refer to Figure 1 for study design.

The study is funded by primary researcher and author Dr Nicholas Noye. The study procedures and consent are in compliance with the NHMRC National Statement, updated May 2015. Ethics approval will be submitted to the Prince Charles Hospital Ethics Board for review and approval.

Figure 1. Study design flow chart



*please see attachments
Version 3.

Patient Selection

Patients will be recruited by emergency department physicians, orthopaedic doctors and Nurse Practitioners employed by the Darling Downs Health Service and working at the Toowoomba Base hospital. Patients with an acute presentation of a shoulder dislocation (< one week since date of injury), aged between 15 and 60 years of age, with access to a smart phone, who are appropriate/able to be treated conservatively via the usual rehabilitation pathway will be eligible for inclusion. Conservative management will be defined as non-surgical management. The Sunchine Coast health district advocates acute relocation followed by a 12 week rehabilitation program. The driving determinants between conservative and surgical management remain the extent of damage to anatomical structures and risk of recurrence however, management is still at the discretion of the patient and surgeon [2,7].

Patients that are not English speaking or with injuries where surgical intervention is indicated/required to obtain stability, i.e. bony lesions, extensive ligament and/or rotator cuff tears, will be excluded.

Sample Size

Our estimated, required sample size for a superiority RCT is based upon the primary outcome of the OSIS questionnaire. We have utilised results from a 2015 Dutch study to ensure our results are clinically significant. This study was the first to assess both the validity and the smallest detectable change (SDC) of the OSIS questionnaire[8]. The SDC refers to the smallest required variance in the OSIS score to correlate to a clinically significant change and was shown to be 9 points with a standard deviation of 9.3. A mean difference between the two groups of ≥9 points would then be considered clinically significant. With the substitution of these statistics into a sample size calculation for superiority RCTs (figure 2.) it is determined that the total number of patients required to account for type I and II errors is 33 [12]. Taking into account a loss to follow-up of 40% the total sample size required is conservatively estimated at 48 patients.

Figure 2. Estimate of Required Sample

$$n = 2\sigma^2\{[\xi_{1-\alpha/2} + \xi_{1-\beta}]/\Delta_A\}^2$$

$\Delta_A = 9.0$ $\beta = 0.2$ $\alpha = 0.05$ $\sigma = 9.3$

$\xi_{1-\alpha/2} = +1.96$ $\xi_{1-\beta} = +0.84$

Size for a superiority RCT

N.B. Calculation is for one half of the total sample size I.e. One trial arm

Recruitment of the Study Participants

The SPACS study will recruit patients from Emergency Departments within the Darling Downs Health District. Potential participants will be identified by the Department of Emergency staff and informed by an emergency physician as to how to apply to take part in the trial. All participants will be given an information sheet explaining how to download the SPACS mobile app using the site specific code. This code will ensure that only participants in the trial have access to the application. Upon downloading the application participants will be shown the consent form (attached 12.2), by pressing agree they will be confirming they have read it and are electronically signing it. A copy of this form will then be sent to the participant's and researchers' emails. With respect to minors, the form clearly states that minors will need parental/guardian approval. If the participant is under 18 contact will be made via email to confirm parental/guardian approval. After the consenting process participants will be required to fill in their personal/injury specific information. Once the patient completes this step they will be automatically randomised to either the control or the intervention arm.

Randomisation Process

Upon registering for the trial, downloading the application and pressing "ENTER" within the application the patient will be randomly allocated to either the control or intervention arm via a random number generator within the app. If the number is even they will be allowed access to the application content and services - the intervention arm. If the patient receives an odd number allocation they will be allocated to the control arm where they will not have access to the application content nor its services.

Participants will only be able to download the application on a device once. If downloaded again the application will maintain the same allocation. In addition the details entered for each participant will be checked at the time of data analysis. If the same participant has downloaded the application on different devices their data will be remove

Interventions

Subjects assigned to the control arm will only have access to a page outlining the details of the trial and the importance of their feedback regarding the questionnaires. They will receive OSIS questionnaires at 0, 3, 6, 12, 24, 52 and 73 weeks from their date of injury as well as access to the usual physiotherapist rehabilitation services supplied by the private and public sectors. The intervention arm will also receive OSIS questionnaires at these times and access to the same physiotherapy but in addition they will have access to the application content. The content made available to the intervention arm will consist of a lay man's explanation of the injury, management and prognosis with accompanying references as well as access to a training module for each individual stage of rehabilitation. These stages will include the "acute", "intermediate" and "strengthening and prevention" modules. Each module has been approved by the orthopaedic physiotherapy team and senior Orthopaedic surgeons within the district. The modules contain exercises pertaining to recent studies proving the efficacy of rehabilitation programs post dislocation [3,4] and the health districts existing program (see appendix). The total duration of the rehabilitation program is 12-16 weeks dependent on the patient's requirements and recommendations from their personal physiotherapist supervising the rehabilitation. The intervention participants will be reminded to complete three rehabilitation sessions a week unsupervised, once considered competent and safe to do so by their physiotherapists. Reminders will be sent to the patient's phone reminding them to complete these exercises. The rehabilitation sessions will not be supervised or recorded. Any additional therapy or conservative management outside of the application will not be monitored or questioned. Both private and public physiotherapists within the district will be made a aware of the study and its protocol.

Risk vs. Benefit

The risks of this intervention have been deemed low to negligible. The efficacy of the rehabilitation exercises has been proven and form the basis of the programs currently being used within the district. The greatest perceivable risk within this study is that of injury during unsupervised rehabilitation sessions. This however is also the case within the current rehabilitation programs where, once deemed competent by the physiotherapist or medical officer, the patient is usually instructed to continue their exercises unsupervised at home. There is potential for the patient to advance themselves too quickly with access to the advanced program from day one. However, again this is commonly the case within current practice and the risks of which will be detailed within the application and the consenting documents. The Benefit of this intervention is A) easy, free, 24/7 access to empirically based rehabilitation exercises and information and B) regular reminders to perform and complete these exercises. With the above considered we believe the benefits of this intervention far outweigh the risks.

Study Outcomes

The primary outcome of the SPACS study is improved shoulder stability measured by the OSIS. As mentioned previously a difference in OSIS score of ≥9 points will be considered clinically significant at the time of the respective questionnaire [8]. The secondary outcome will be that of shoulder surgery due to failure of conservative management.

Method of Assessing Patients

The Oxford Shoulder Instability Score has been selected as the primary assessment tool because of its ease of use and excellent validity in reliability, clinical correlation and comparability to other popular scoring systems [8,9]. The OSIS is a 5-option response (Likert scale) 12 question questionnaire, with each response scored from 0 to 4, with 4 being the best outcome. The overall score is reached by simply summing the scores received for individual questions. This results in a continuous score ranging from 0 (most severe symptoms) to 48 (least symptoms) [9]. The final questionnaire at 73 weeks will also include a binomial question as to whether or not the patient has required surgery to their shoulder due to continued or worsening instability. It will also include a question rating their perceived compliance to the rehabilitation program and helpfulness of the application.

Baseline Data

The baseline data collected at registration will include; name, sex, date of birth, date of injury, traumatic or atraumatic mechanism and email address. The patient will then complete their first OSIS questionnaire. At the conclusion of OSIS data collection (18 months) participants that have supplied adequate questionnare data to allow analysis will be invited to fill out a patient health questionnaire. This questionnare will assist in further defining the impact that lifestyle and co-morbid factors have on rehabilitation and outcome.

Data Collection and Storage Procedures

All data will be collected via the application and stored within a Queensland Health email account specific to the trial. From collection to analysis the data will be de-identified by a numbered ID specific to each individual patient and assigned/created by the application. The data will be collated and inspected by the second author on a bimonthly bases in an attempt to separate duties - between the collector and the collator- and ensure ongoing successful collection. Once the data is collated it will be stored within a Queensland Health, password protected Excell spreadsheet.

Due to the study design and use of a mobile application for data collection both recruitment and data collection will occur simultaneously and will be highly dependent on patient compliance. Recruitment will persist through the first 12-14 months of the trial, while data collection the total 18 months. This approach has been adopted in order to maximize our data points per patient and therefore the probability of identifying a significant correlation between intervention and patient. With maximal data points over up-to 12-18months the results will also be comparable to a wider range of existing reviews and publications which commonly compare longer term outcomes such as 12month re-dislocation rates.

The application will be designed by Reubro International, Cochin, India. As such the application will be the private property of the lead researcher Dr Nicholas Noye and there will be no access available to the developer. Furthermore, no data will be stored on the application to ensure further security of the information regardless of its non-sensitive nature. A non-disclosure and confidentiality agreement was entered into with the developer upon commencement of business/communication and development.

Compliance Measures

The only active compliance measures will be that of the questions within the questionnaires pertaining to the patient's perceived adherence to their program.

Analyses

Analyses of the data will take place after the completion of the trial. Descriptive statistics will be used to describe the baseline statistics, demographics and outcomes. Cox-regression analysis will be used to compare the outcomes of the two trial arms. All analyses will be adjusted for prognostic factors such as age, sex and mechanism.

Study Monitoring, Auditing and Inspecting

The supervision of the patients rehabilitation will be carried out by their particular treating therapist and/or medical officer as per usual. Patient's emails will be confirmed twice upon registration and a confirmation email sent. Data entry will occur through the the trial to record and assess the response rate. If the response rate falls below 80% a review of the application's function and performance will be done to ensure the push notifications are occurring and a generic email sent to the participant's requesting A) the report of any problems and B) to complete the questionnaires.

Conflicts of Interest

No conflicts of interest have been identified within this self-funded study. No financial benefit will be gained from this research. The application and any associated intellectual property is owned by the primary investigator Nicholas Noye.

Study Timetable and Publication Plan

SPACS looks to have completed their application to the Prince Charle's Ethics board by June 2017. Recruitment will be pending ethics approval with a tentative date of July 2017. Data collection will end in mid 2019 with the aim of analyzing and publishing by years end. Note these dates are tentative and may change pending ethics and site approval.

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Attachments

12.1 Tables
12.2 Informed consent documents
12.3 Patient Education Brochures
12.4 Questionnaires or Surveys
12.5 Budget
12.6 Accompanying Licenses
12.7 Authorities