JT REHAB LTD

Short title: S-Press

Sponsor code: JT Rehab-01

IRAS number: 251647

S-Press research project proposal

(clean version)

Full title of investigation:	Efficacy, feasibility, usability, and acceptability of the S-Press leg strengthening device for strengthening leg muscles and improving physical impairment of older adults.
Short title:	S-Press evaluation
Version of research project proposal	Version 11.2 NHS. - clean version 01/12/2020
Sponsor:	JT Rehab Ltd
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Sponsor of study

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Summary of the study proposed:

The proposed study will examine the use and effectiveness of a novel strength training device – The S-Press within an NHS environment. The S-Press is a portable exercise device that can be used seated or lying down and specifically targets the knee extensors and flexors. The knee extensors are particularly important in the performance of activities of daily living such as rising from a chair, walking up and down stairs and walking.

Resistance training is the most effective strategy to help to reduce muscle wasting in response to ageing or chronic disuse; however as current in-patient settings likely fail to produce an overload stimulus to the muscle for hypertrophy and strength gains, there is a need to develop new interventions and equipment to help deliver this. The S-Press is designed by a Physiotherapist with the goal of increasing muscle strength and improving physical function in patients who may be confined to their bed or chair or unable to join in with standard physiotherapy treatments.

This mixed methods study will examine the efficacy of the S-Press to improve muscle size using B-Mode Ultrasound and physical function, using sit to stand x5 with use over 6 weeks, alongside the qualitative experience of the use of the S-Press through a one to one semi structured interview. Data collected will enable CE marking of the device along with the existing data collected and enable onward NHS studies.

This novel device should improve outcomes for users, with the eventual aim of easing pressure on NHS staff and produce NHS cost savings by helping prevent delays in discharge which cost the NHS £820 million each year.

Background and scientific justification:

Prevention of hospital associated deconditioning is an immediate healthcare unmet need. 10.5 million vulnerable older adults are admitted into UK hospitals annually. Muscle deconditioning begins within 2 days, with baseline strength reducing by up to 20% in 1 week and 68% of patients discharged below their pre-admission level of function (Kortebein et al., 2008; Falvey et al., 2015). These patients are 3x more likely to be re-admitted within 30 days and de-conditioning is responsible for 47% of delayed discharges (Lim et al., 2006).

Preserving muscle strength and function has many contributing factors; with physiotherapy having a key role. Progressive resistance exercise (PRE) is known to increase muscle strength in even the

frailest individuals (Suetta et al., 2007) and researchers suggest that PRE should be used more in hospitals to prevent deconditioning and improve outcomes (Falvey et al., 2015). There is limited PRE equipment available for physiotherapists, its use compounded by a lack of clinical time and staff. The new S-Press portable leg strengthening device has been designed by a physiotherapist to improve access to effective PRE for vulnerable older patients and ease workload for physiotherapists.

PRE benefits have been well documented since the 1950s, yet physiotherapists working in hospitals rarely use it with patients. There are many reasons for this including health barriers, institutional barriers, changing demand on physios within the NHS and lack of appropriate equipment for effective use. Guthrie Smith (1943) invented the revolutionary sling/spring suspension format used for decades by physiotherapists. The S-Press utilises this tried and tested principle in a re-imagined /re-designed mechanical gym-equipment style, for portability, accessibility and use by vulnerable temporarily immobile patients in need of muscle strengthening if confined to their bed or chair.

Leg muscle weakness, especially knee-extensor strength, is associated with increased falls risk (Tinetti 1988; Wolfson 1995) and decrease in function (Van Roie et al., 2011). Leg strength gain is associated with improvements in sit to stand, gait, transfers, stair climbing and confidence (Chandler 1998). A study is needed to assess if providing PRE to older adults via use of the S-Press device has a beneficial effect on muscle strength and if this translates into functional task improvement.

PPI using expert patients and clinicians from three NHS Trusts have participated in focus groups. A national proof of market study run by NIHR Devices for Dignity has shown a positive response to the S-Press concept and recognition of its potential value. These discussions have all contributed to the final S-Press design decisions and features. In-patient feedback on physiotherapy interventions describes a feeling of achievement and a sense of doing 'real physio' when using exercise devices, as compared to ‘just walking’. Competition between patients is also known to be beneficial and encourages participation and improvement; all achievable with S-Press use.

Success criteria will be to show clinically significant improvements in lower limb muscle size, sit to stand ability of 15 - 20 older adults, and the views on use and acceptability with users and staff, following 6 weeks of training with the S-Press. Evidence that this improvement in lower limb muscle size and strength transfers to an improvement in a range of selected validated functional skills and sufficient user qualitative feedback will allow CE marking of the device enabling further NHS studies.

The project lead and S-Press inventor is a physiotherapist with 22 years of older people’s rehabilitation experience. Researchers from Sheffield Hallam University will devise, run, and analyse the quantitative data from the study. The qualitative element of the real-world evaluation will be

performed and analysed by the research team at Northamptonshire Healthcare NHS Trust. Devices for Dignity have previously provided proof of market evidence and will provide regulations assistance, health economics and commercialisation to enable CE marking. S-Press development has been funded by Versus Arthritis.

To gain CE mark as a class 1 medical device a clinical evaluation needs to be performed with older people. NHS patients will be perfect participants to trial this fully safety tested exercise device.

Description of intended purpose and mode of action of device:

The S-Press is a mechanical single leg strengthening device, using spring resistance to provide a progressive increase in resistance level from 3kg to 20kg resistance level. The S-Press requires physical effort from the user to work, through a push or pull action of the leg whilst the leg is positioned on a supportive leg rest. The S-Press can be used on the bed or positioned on the floor if user is sitting in a chair. The intended purpose of the S-Press is to strengthen the quadriceps and hamstring muscles and provide improvement in the physical ability of the user, such as sit to stand, transfer and walking ability.

Research aims:

To assess the efficacy, feasibility, usability, and acceptability of use of the *S-Press* by NHS staff using it with an older NHS in-patient population, for strengthening quadriceps and hamstring muscles and improving physical impairment.

Research objectives:

Primary Objectives:

The primary objectives are to quantify changes in the following in response to 12 sessions (2x per week for 6 weeks) of using the S-Press device supervised by a Physiotherapist. The primary outcomes are to assess:

- Functional improvements using the 5x sit to stand test.
- Morphological changes, measuring muscle thickness of the Vastus Lateralis and Rectus Femoris muscle using B-Mode ultrasound.
- Any safety issues with *S-Press* use with older users.
- Perceptions of usability of the *S-Press* with older adult users and care givers.

Secondary Objective:

- To meet CE marking requirement
- To enable further follow-on evaluation in different NHS environments
- Commercialisation.

Type of study design:

This is a single-arm, mixed methods study design. Quantitative and Qualitative research methods planned.

Purpose of the study:

To gain user data for feasibility of use and acceptability in the NHS environment and safety and efficacy to enable CE marking for further follow-on NHS studies.

Study classification:

Efficacy and feasibility study.

Sample size justification:

For the study we will aim to recruit 15 – 20 NHS in-patient participants across the 4 sites. Sample size aligns with previous research studies using similar methodology (e.g., Dibble et al. 2006; Alkner, et al., 2004; Frontera, et al., 1988; Fiatarone, et al., 1990; Grimby, et al., 1985; Pyka, et al. 1994; Hagerman et al. 2000; Hepple, et al. 1997)

Typical exercise training studies of this length have 10-15 participants per arm of the trial. This would conventionally include a control group. As this is a feasibility trial, the advice from our RDS was that a control group was not required. An *N* of 12 has been recommended as a minimum number of participants per group to be recruited for a clinical trial where there is no prior information to guide sample size (Julious 2005). This figure is suggested to represent the lower threshold required to estimate the standard deviation of measures with adequate precision. We aim to recruit 15 – 20 participants to the study to allow for a predicted 20% attrition rate.

This low number of patient participants per site will provide a low burden for the staff participants.

Number of centres justification:

Four NHS sites have requested to participate, this will ensure enough participants are able to be recruited who are able to provide informed written consent to be included and maintain a low burden for the participating ward staff.

Justification for NHS staff involvement and numbers:

The role of the NHS physio team is to enable the fastest recovery of sit to stand and transfer ability to enable speedy discharge of in-patient's home to a familiar environment. Strengthening exercise provision is a standard treatment provided for this purpose, limited in many Trusts by availability of appropriate equipment. Provision of several free exercise devices per site that can deliver effective, specific, sit to stand muscle strengthening for the length of the trial, is a good benefit to the staff and the patients. The number of patient participants is being kept at a low level of 4 patients per site. Senior management have buy-in from the staff and have appropriate safe staffing levels available to participate in the study. Number of exercise sessions will be twice a week to follow national recommendations for strength training, for approximately 30 minutes. Patients are seen daily on the ward for therapy intervention including strengthening and mobility work. Daily, 30-minute sessions are the gold standard for daily therapy interventions.

No specific number of staff participants has been set to be recruited, so there is no added pressure for participation. There will be 2 devices per site available so a minimum of 2 staff members per site is preferred for the study to maximise the benefit and use of the S-Press and for feedback.

Duration of study – justification

The time course of adaptations in muscle strength, mass and function is complex. During the first weeks of strength training, the brain responds to training by recruiting more motor units with each muscle contraction. This increases the force you can generate. It also increases how rapidly these motor units fire, this is called neuromuscular adaptation. After 4 to 6 weeks of training, if the muscles have been challenged sufficiently, the muscle fibres will start to increase in size, this causes a greater increase in muscle strength as the muscle cross-sectional area enlarges or "hypertrophies".

Previous research studies (Dibble et al. 2006; Alkner, et al., 2004; Frontera, et al., 1988; Fiatarone, et al., 1990; Grimby, et al., 1985) using resistance exercise show a varied duration. Most commonly studies of between 10 – 12 weeks are performed. The S-Press research study will perform resistance exercises for a 6 -week period. This is the amount of time that the patients are in-patients on the ward and gives enough time to observe changes in strength and muscle fibres over this time.

The study will be completed by June 2022.

Criteria for participant selection:

1 - NHS in-patients – quantitative and qualitative arms of the study

Inclusion criteria:

- Any in-patient admitted onto the ward sites for therapy intervention, assessed as medically stable and physically able to participate by nursing staff and able to provide informed written consent for participation.

The implications of joining the study will be discussed with the participant to ensure full understanding. Written documentation with explanation of study will be left with participant for relatives/carers information.

Exclusion criteria:

- Any patient who is unable to give informed consent.
- Significantly confused patients - may not understand or retain the information to perform the exercises so will be excluded from this study.
- Patients with unstable or deteriorating medical conditions or are acutely unwell with an infection.
- Patients unable to do leg press exercise
- Patients who have had major surgery or myocardial infarction within the past 6 months.
- Patients who have major surgery scheduled during the intervention period.
- Patients currently undergoing treatment for cancer
- Patients who currently have high blood pressure that is uncontrolled (Systolic >200mmHg or Diastolic > 110mmHg)
- Patients with a physical disability that precludes safe and adequate testing.
- Patients with acute pulmonary embolism, infarction, or deep venous thrombosis.

2 - NHS Staff – Qualitative arm of the study only

Inclusion criteria:

- Any NHS staff delivering therapy care to in-patients (for example: qualified physiotherapists, physiotherapy assistants or technical instructors, trained nurses, clinical support assistants, and activity co-ordinators).

Staff will be trained to set up and deliver the S-Press exercise session with the patients. This should constitute minimal additional work burden as they would be exercising with these patients during their normal 30-minute physio session and will give alternative therapeutic options for treatment sessions.

Exclusion criteria:

- Any staff who do not deliver therapy care (for example catering and domestic staff).

Criteria for participant withdrawal

Participants (both NHS staff and in-patients) may voluntarily withdraw from the study at any point. Participants will be informed that their participation is voluntary and that they may withdraw from the study at any time without giving a reason and without it affecting their clinical care or legal rights. Any data provided to that point will be used unless the patient requests otherwise. If the patient requests to have their data withdrawn, all data relating to that participant will be securely destroyed. From a clinical perspective, any in-patient participant that experiences an adverse event will be removed from the study. During exercise sessions, heart rate and blood pressure will be monitored, and where necessary sessions ceased. For blood pressure measures, exercise sessions will be stopped a systolic blood pressure measurement of >210mmHg for men and >190mmHg for women or a decrease of systolic blood pressure >10mmHg from resting values will be considered as stop points (American College of Sports Medicine, Guidelines for exercise testing and prescription, 10th Edition). The occurrence of such event will be classed as criteria for withdrawal from the study on safety grounds.

There is a very small chance of joint injury around the knee or an increase in pain associated with osteoarthritic joints. Knee injury risk will be reduced by the supervision of sessions and individualised set up of the S-Press device. A significant increase in joint pain resulting from using the device will be a withdrawal criterion.

Should participant withdrawal occur, this will be followed-up by the chief investigator and documented with the study findings.

Description of the generally recognised medical diagnosis for investigational testing

The generally recognised medical diagnosis of muscle weakening due to the de-conditioning effect, post injury or illness, and sarcopenia and natural age-related muscle weakening is being proposed for the study.

Proposed post-market clinical follow-up plan:

There is no specific post-market follow-up set up yet due to this being a preliminary efficacy and feasibility study.

On-going evaluation of products on the market will be performed through planned customer feedback and customer services. Only through constant systematic market surveillance (post-market surveillance) can JT Rehab guarantee that the S-Press provides the promised benefit to patients as well as the lack of any unrestrained risks.

If "regular market surveillance" does not provide sufficient data, post-market clinical follow-up studies regarding the manufacturer may become necessary.

To meet MDR requirements, JT Rehab will design and run PMCF studies with three major goals in mind:

- Confirming device safety and clinical performance
- Ensuring continued acceptability of identified risks
- Detecting emerging risks based on factual evidence

Physiological Assessments (Quantitative Data)

These assessments will be conducted at baseline (start) and at the end of the intervention period (6 weeks). Post testing will be conducted 48-72 hours post final exercise session to allow for any fluid changes within the muscle to subside and minimise fatigue of participants. There will be a familiarisation session for all participants prior to completing the baseline assessments to minimise any learning effects of the assessments.

Familiarisation

Following obtaining informed consent, participants will be provided with an opportunity to have a practice attempt/s at each of the assessments and also the exercise session. For the exercise sessions this will be used to identify the starting point in terms of resistance for each individual. All exercise sessions and assessments will be performed on the ward minimising extraneous travel costs for participants.

The physiological assessments are as follows:

Muscle thickness

The muscle thickness of the Vastus Lateralis and Rectus Femoris of each leg will be determined by B-Mode Ultrasonography (Healcerion, UK), this will be conducted by a qualified member of the research team with the appropriate skills and training. The measurements will be conducted at 50% of femur length, determined by the distance between knee joint space and greater trochanter as defined by palpation. Muscle thickness will be quantified using ImageJ (NIH, USA) post-hoc. Images will be saved on the Healcerion system as anonymised codes, i.e. SPRESS-1-Pre. Images will then be anonymised and coded by another member of the team before being analysed blindly by Dr Tom Maden-Wilkinson (Co-I), using ImageJ Software (NIH,USA)

5 x sit to stand

In-patient participants will be timed for how long it takes them to complete 5x sit to stand. Participants will be allowed to use their ambulatory aides if required and this noted. Participants will have an investigator near them to prevent an adverse falls or loss of balance. Where this takes longer than 60s, the number of complete movements and the time it took for those will be recorded. Participants will be asked to complete this 3x if possible, with sufficient rest in between each attempt, to enable an average to be taken.

Exercise Sessions

First, participants will be asked to warm up supervised by the physiotherapist, this will incorporate some low intensity range of movement exercise and light stretching.

Staff participants will set up the patient participant using the S-Press protocol for set up. Patients can remain on the bed or in the chair so will not require transferring or position change by the staff for use.

Initial assessment of appropriate resistance level will be examined at the beginning of the first session, by assessing the patient participants 1 repetition max (1RM) level (maximum resistance level ability - Instructions stated in set up protocol).

Participants will then complete 3 sets of 10 repetitions on each leg firstly for the knee extensors and then the knee flexors. The S-Press allows both Concentric and Eccentric muscle actions, so muscle groups are performed independently. A guide of 1 minute's rest will be provided in between sets and legs, although more rest will be allowed if required by the participants. The amount of time per exercise session will be approximately 30 minutes.

Blood pressure and heart rate will be measured before the exercise session begins, mi-way through and again at the end of the session. This is to ensure that there is maintenance of optimal levels of blood pressure and heart rate and monitoring of any adverse effects. These measurements are regularly taken by therapy staff to assess their patients' conditions before and during physical intervention.

Data from the assessments will be analysed using paired *t*-tests. As this trial is an efficacy and feasibility trial descriptive statistics (mean, standard deviation and % Change) will be calculated. In addition, Cohen's *D* will be used to determine effect sizes to quantify the magnitude of any differences in variables. A *p* value of $p<0.05$ will be used to determine significance, with effect size of <0.2=small; 0.5= moderate; >0.8 large.

Data collection – for Qualitative study aspects

The 15-20 NHS in-patient participants who have participated in the 6-week exercise trial will be invited to consent to a one-to-one semi-structured interview by telephone or online if able (due to Covid-19 restrictions), to explore their experience of the usability and acceptability of the device.

The clinician/PI will provide patient with PIS and consent statement for them to read. If a patient agrees to participate, the interview will be scheduled no sooner than 48 hours afterwards, to ensure time for consideration

On the interview date, the participant will be invited to provide informed verbal consent. This consent will be recorded on a separate recorded file, which will be stored on a secure NHS server.

Any participants whom the NHS staff identify as requiring communication support to understand and/or answer questions will be offered the option of nominating a friend or relative to support them in the answering the interview questions.

NHS staff who have observed at least one treatment session will also be invited to participate in a semi-structured one to one interview by telephone or online (due to Covid-19 restrictions) to explore their perspective on usability and feasibility of the device within the setting they work in. No set sample size target is set for this group to ensure staff do not feel under any obligation to take part. The Ward Managers have considered their staffing levels and consented to participation of eligible staff where informed consent is given.

Objectives:

To explore feasibility, usability, and acceptability of the device with:

- NHS staff who have supported the 15-20 in-patient participants who have used the device
- 15-20 in-patients who have used the device

Semi-structured interviews will be undertaken with both the staff and patients, on a one-to-one basis. The interviews will be recorded and transcribed verbatim.

Analysis:

Qualitative Thematic Analysis will be undertaken, as informed by Braun and Clarke (2006) involving a 6-step framework analysis approach. Interviews will be coded using *a prori* topical codes according to the three assessment areas of interest, feasibility, usability, and acceptability. NVivo will be used to organise and analyse the data. The 6-steps followed will be:

1) Familiarisation with the data: Data will be transcribed, read, and re-read, and initial codes noted. Any missing or ambiguous data will be resolved at this stage.
2) Generating initial codes: Interesting features across the data set will be coded, and data relevant to each code collated.
3) Searching for themes: Codes will be collated into potential themes, and the data relevant to them gathered. A theme index of the themes and subthemes will be created.
4) Reviewing themes: Themes will be assessed, combined, refined, separated, and discarded accordingly. A framework will be developed which comprises a matrix for each theme.
5) Defining and naming themes: Operationalisation of each theme and subtheme and a clear working definition that capture the essence of each theme will be developed.

6) Producing the report: The overall learning from the qualitative data analysis will be presented in a report summarising the themes and illustrating these with noteworthy (anonymised) quotes and tables of descriptive quantitative data.

This process will be completed with attention to the guidance on principles of Credibility, Transferability, Dependability and Confirmability (Cochrane Collaboration Qualitative Methods Group, 2011), and following guidelines by Shenton (2004).

Serious adverse event reporting:

Potential adverse events that are common to novel physical activity such as delayed muscle soreness, feeling faint as well as temporary increases in heart rate, breathing rate and blood pressures, are planned for within the study and risk minimized with a thorough warm up and cool down with participants as well as supervision throughout the session.

There is a very small chance of joint injury around the knee or an increase in pain associated with osteoarthritic joints. Knee injury risk will be reduced by the supervision of sessions and individualised set up of the S-Press device. A significant increase in joint pain resulting from using the device will be a withdrawal criterion.

Although there is a risk associated with physical activity, numerous studies have shown that physical activity is safe, and beneficial to the health of patients in this environment (Henskens et al., 2018; Kalinowski et al., 2012). The most severe risks associated with physical activity are death or serious cardiac event (Vuori 1986).

Increasing or maintaining skeletal muscle mass has also been shown to increase quality of life and reduce the incidence of MSK injuries caused by trips and falls (Skelton & Beyer 2003).

Participants will be made aware of all the processes involved in data collection stages before the beginning of the study. Individual clinicians will be aware of their medical history and will have up-to-date training on first aid and dealing with any adverse events that could potentially occur.

Individual sessions will be postponed or cancelled if an individual is feeling unwell. If the session has started and participants suddenly feel ill whilst performing exercises or they experience tissue viability issues to do with skin integrity or damage caused by the S-Press or signs of cardiac event, then nursing staff will be alerted and session ended. Any adverse event, serious or not will be reported back to nursing staff and reported with the daily log and data collection sheets.

Data will be collected in line with the NIHR guidance on good clinical practice. The PI will ensure the study is carried out in accordance with the protocol (equipment calibrated, facilities suitable and

health and safety measures in place). All correspondence with participants will be recorded in the site file, and any adverse findings, procedural errors or amendments to the protocol will be explained in detail to participants as soon as possible. All deviations will be reported to the MHRA.

Alkner, B.A., & Tesch, P.A.,(2004). Efficacy of a gravity-independent resistance exercise device as a countermeasure to muscle atrophy during 29-day bed rest. *Acta Physiologica Scandinavica*, 181(3), 345-357.

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative Research in Psychology, 3(2), 77-101.

Chandler, J.M., Duncan, P.W., Kochersberger, G,, Studenski, S. (1998). Is lower extremity strength gain associated with improvement in physical performance and disability in frail, community-dwelling elders?*Archives of Physical Medicine and Rehabilitation,* 79(1), 24-30.

Charette, S.L., McEvoy, L., Pyka, G., Snow-Harter, C., Guido, D., Wiswell, R.A., Marcus, R. J (1985). Muscle hypertrophy response to resistance training in older women. *Journal of Applied Physiology,* 70(5), 1912-6

Dibble, L.E., Hale, T.F., Marcus, R.L., Droge, J., Gerber, J.P.,& LaStayo, P.C. (2006). High-intensity resistance training amplifies muscle hypertrophy and functional gains in persons with Parkinson's disease. *Movement Disorders*, 21(9), 1444-52.

Falvey, J. R, Mangione, K.K., & Stevens-Lapsley, J.E. (2015). Re-thinking hospital-associated deconditioning: proposed paradigm shift. *Physical Therapy,* 95(9), 1307-1315.

Fiatarone, M.A., Marks, E.C., Ryan, N.D., Meredith, C.N., Lipsitz, L.A., & Evans, W.J. (1990). High-intensity strength training in nonagenarians. Effects on skeletal muscle. *Journal of the American Medical Association*, 263(22), 3029-34

Frontera, W.R., Meredith, C.N., O'Reilly, K.P., Knuttgen, H.G., & Evans, W.J. (1988). Strength conditioning in older men: skeletal muscle hypertrophy and improved function. *Journal of Applied Physiology,* 64(3), 1038-44.

Grimby, G., Aniansson, A., Hedberg, M., Henning, G.B., Grangård, U., & Kvist, H. (1992). Training can improve muscle strength and endurance in 78- to 84-yr-old men. *Journal of Applied Physiology*, 73(6), 2517-23.

Hagerman, F.C., Walsh, S.J. Staron, R. S., Hikida, R.S., Gilders, R.M., Murray, T.F., & Ragg, K. E. (2000). Effects of High-Intensity Resistance Training on Untrained Older Men. Journal of Gerontology, 55A(7), B336-B346

Hepple, R.T., Mackinnon, S.L., Goodman, J.M., Thomas, S.G., & Plyley, M.J. (1997). Resistance and aerobic training in older men: effects on VO2peak and the capillary supply to skeletal muscle. *Journal of Applied Physiology*, 82(4), 1305-10.

Kortebein, P., Brock Symons, T., Ferrando, A., Paddon-Jones, D., Ronsen, O., Protas, E., Conger, S., Lombeida, J., Wolfe, R., & Evans, W.J. (2008). Functional impact of 10 days of bed rest in healthy older adults. *Journal of Gerontology: Biological Sciences,* 63(10), 1076-81.

Lim, S.C., Doshi, V., Castasus, B., Lim, J.K., & Mamun, K. (2006). Factors causing delay in discharge of elderly patients in an acute care hospital. *Annals of the Academy of Medicine of Singapore*, 35(1), 27-32.

Pyka, G., Lindenberger, E., Charette, S., Marcus, & R. J Gerontol. (1994). Muscle strength and fiber adaptations to a year-long resistance training program in elderly men and women. *Journal of Gerontology,* 49(1), M22-7.

Shenton, A. (2004). Strategies for ensuring trustworthiness in qualitative research projects. *Education for Information*, 22(2), 63-75.

Suetta, C.; Magnusson, S.P., Beyer, N., & Kjaer, M. (2007) Effect of strength training on muscle function in elderly hospitalised patients. *Scandinavian Journal of Medicine & Science in Sports*, 17(5), 464-72.

Tinetti, M.E., Speechley, M., & Ginter, S.F. (1988). Risk factors for falls among elderly persons living in the community. *The New England Journal of Medicine,* 319,1701-1707.

Van Roie, E., Verschueren, S.M., Boonen, S., Bogaerts, A., Kennis, E., Coudyzer, W., & Delecluse, C. (2011). Force velocity characteristics of the knee extensors: An indication of the risks of

physical frailty in elderly women. *Archives of physical medicine and rehabilitation,* 92(11), 827-1832.

Wolfson, L., Judge, J., Whipple, R., & King, M (1995). Strength is a major factor in balance, gait, and the occurrence of falls. *Journal of Gerontology,* 50A, 64-67.