

Title

App-based supplemental exercise does not improve functional outcomes in rehabilitation: a randomised controlled trial

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Abstract

Background: Physical activity levels of individuals in rehabilitation are low. Supplemental exercise programs can encourage meaningful physical activity outside of structured therapy time. mHealth and other novel technologies offer a method via which this can be delivered. This randomised controlled trial investigated whether the use of an app-based supplemental exercise program leads to greater functional improvements compared to usual care physiotherapy in a rehabilitation setting. It also examined the uptake of an app-based supplemental exercise program and whether factors, specifically different health conditions, may impact the effectiveness of such a program.

Methods: Participants were randomly allocated to usual care physiotherapy (control) or usual care physiotherapy with the addition of an app-based supplemental exercise program. Primary outcome measures were walking speed measured via the 10 Metre Walk Test (10mWT) and level of disability measured via the Functional Independence Measure (FIM). Secondary outcome measures included walking endurance measured via the Six Minute Walk Test (6MWT), functional mobility measured via the Timed Up and Go (TUG) test and length of stay (LOS). Total supplementary exercise dosage (measured in repetitions and time) was assessed for the intervention group.

Results: There were no significant differences between the groups in terms of primary and secondary outcomes with no difference in change scores for walking speed (mean difference -0.5m/s, 95% CI -5.8 to 5.9) and disability (mean difference on FIM -0.9, 95% CI -3.6 to 1.8). Participants in the intervention group performed an additional 7 min (SD 9) and 49 repetitions (SD 48) of supplementary exercise per day.

Conclusion: An app-based exercise program can facilitate a small supplementary exercise dose. However, the addition of an app-based exercise program in rehabilitation does not affect functional outcomes when compared to usual care.

Keywords

mHealth, exercise therapy, physical therapy, rehabilitation, outcomes

Background

Intensive therapy is associated with improved outcomes in rehabilitation.¹ Therefore, an individual's activity during rehabilitation is central to restoration of function.¹ Studies in both stroke and orthopaedic inpatient rehabilitation settings have found that levels of physical activity completed are low.^{2, 3, 4, 5} As an example, 62% of individuals in hospital post stroke do not meet the recommended physical activity guidelines.⁶ Furthermore, individuals participating in rehabilitation are likely to spend almost half of the day inactive,⁷ with those in rehabilitation post stroke sedentary for nearly three-quarters (74%) of the day.⁸ Individuals participating in rehabilitation tend to be more active during therapy time⁹ and participate in an average of one hour of physiotherapy per day.⁷

Methods to provide meaningful physical activity outside of structured therapy time should be considered in order to promote a greater dosage of exercise.^{10, 11} Supplemental exercise programs are acceptable to individuals in hospital and have been described as enjoyable and beneficial.⁷ Research shows that supplemental exercise programs have the potential to improve functional outcomes, although adherence tends to be low.¹² Innovative approaches are required to booster adherence to these supplemental exercise programs.

Mobile health (mHealth) offers an avenue of delivering more engaging independent exercise programs in rehabilitation settings. mHealth is the practice of delivering medicine and public health via mobile technologies. It is a new and emerging area of healthcare¹³ with the benefits of accessibility, affordability, convenience and sustainability.¹⁴ As a novel approach, mHealth can provide an enriched environment for rehabilitation, thereby increasing independent activity.¹⁵ Video- and computer-based interactive exercises can increase exercise dose in a safe and feasible manner by providing opportunity for engagement in exercise.¹⁶ Despite this, there is minimal research into the use of mHealth to improve healthcare delivery in hospital settings.

To our knowledge, there are two recent feasibility studies that have implemented technology to facilitate increased physical activity in an inpatient rehabilitation setting.^{16, 17} A recent pilot randomised controlled trial conducted by our team examined the addition of an app-based supplemental exercise program to usual care physiotherapy in an orthopaedic population and found it to be successful in increasing activity levels in a feasible and safe manner.¹⁷ Another study found that the addition of video- and computer-based exercises to usual rehabilitation was a safe and feasible approach to increase exercise dose in an inpatient geriatric and neurological rehabilitation population.¹⁶

This study aimed to determine if use of an app-based supplemental exercise program would result in greater functional improvements compared to usual care physiotherapy in a rehabilitation setting. It also examined the uptake of an app-based supplemental exercise program and whether factors, specifically different health conditions, may impact the effectiveness of such a program.

Methods

Data were collected between January and December 2018. The study was approved by the Northern Sydney Local Health District Human Research Ethics Committee (HREC/16/HAWKE/444). The study was prospectively registered with the Australian New Zealand Clinical Trial Registry (Registration No.: ACTRN12617001576314). It was conducted in accordance with CONSORT guidelines.

Trial Design

This randomised controlled trial was developed following the completion of a pilot trial that utilised an app-based supplemental exercise program to successfully increase activity levels in orthopaedic rehabilitation.¹⁷ A power analysis completed a priori and based off the pilot trial determined that 140 participants were required to demonstrate a between group difference.

Participants in this study were randomly allocated to one of two groups – usual care physiotherapy or usual care physiotherapy with the addition of an app-based supplemental exercise program. Randomisation was performed according to odd or even numbers (1-200) picked from a concealed box by a member of the research team. Baseline data and objective measures were collected upon entry into the trial. Follow-up data were collected upon discharge from the facility. Participants and some members of the research team were not blind to group allocation due to the nature of the trial. The treating therapist was not blind to group allocation as they were required to design the supplemental exercise program. The researcher involved in performing the baseline and follow-up assessments was blind to group allocation.

Participants

Participants were inpatients at Royal Rehab Private Hospital, a subacute rehabilitation hospital based in Sydney. Participants were screened and invited to participate in the trial if they met the inclusion criteria. To be eligible for inclusion into the trial, individuals were required to be over 18 years of age; inpatients actively engaged in rehabilitation at Royal Rehab Private Hospital; able to give informed consent (as assessed by Mini-Mental State Exam (MMSE) score of more than 24/30); and have no medical contraindications to an exercise program. Individuals were excluded if they had a cognitive impairment preventing informed consent (as assessed by MMSE less than 24/30); a language impairment causing insufficient communication skills to provide informed consent; were pregnant or intending to become pregnant.

Interventions

Both groups received usual care physiotherapy for the length of their stay in rehabilitation. This consisted of individual and/or group therapy in the rehabilitation gym. Participants allocated to the intervention group received additional app-based exercise program (Pt Pal™, California, USA) prescribed by the treating physiotherapist. Each participant in the intervention group was provided with an iPad (Apple Inc., California, USA) for the length of their stay in order to complete the exercise program. They were shown how to use the Pt Pal™ app by a research assistant upon commencing the program. The research assistant provided ongoing technological support as required. The exercise program was upgraded by the treating therapist at their discretion. Therapists were supported by the research team and encouraged to promote use of the app amongst the intervention group participants. A clinician portal allowed the treating therapist and research team to track frequency of use, repetitions performed, time spent performing exercise and provided other clinical information such as pain and ease of performing an exercise.

Outcomes

The primary functional outcome measures were walking speed (m/s) measured with the 10 Metre Walk Test (10mWT) and disability measured with the Functional Independence Measure (FIM).

The 10mWT assesses walking speed over ten metres and is often used as a quick functional outcome measure in rehabilitation. It has shown excellent test-retest reliability,¹⁸ and excellent intra- and inter-rater reliability in the post-stroke population.^{18, 19} The 10mWT was performed over a marked track with a lead-in and follow-through distance of two meters. Participants were asked to walk at their maximal walking speed.

The FIM instrument is a basic assessment of disability and is used to evaluate the functional status of individuals during an episode of hospital rehabilitation.²⁰ It measures 18 items over two subscales (motor and cognition), on a seven-point ordinal scale. The FIM is reliable when used by trained inpatient medical rehabilitation clinicians.²¹

Secondary outcome measures included walking endurance measured with the Six Minute Walk Test (6MWT), mobility measured with the Timed Up and Go (TUG) and length of stay (LOS). Total supplementary exercise dosage (measured in repetitions and time) was also assessed for the intervention group.

The 6MWT is a sub-maximal test used to assess aerobic capacity and endurance. It has shown excellent test-retest reliability in the stroke population.²² The test was performed over a marked track of 30 metres.

The TUG is a reliable and valid measure of functional mobility.²³ This test is commonly used in clinical settings as it is simple and quick to perform.²⁴ A standardised chair was used for the test. The time taken for the participant to stand, walk three metres, turn around a cone and return to sit in the chair was recorded.

LOS was calculated from admission and discharge dates. These data were obtained from the hospital electronic medical records.

App usage data including exercise dosage data were recorded automatically each time an intervention group participant performed exercise on the app. Data were retrieved by the Pt Pal™ team and collated on a secure spreadsheet. All data were sent through to the research team periodically and transferred into the central research database.

Statistical Methods

Statistical analyses were conducted using SPSS Version 25 (IBM Corp., New York, USA). Independent samples t-tests were used for all between-group analyses. Paired-samples t-tests were used for within-group analyses. ANOVA testing was used to examine differences in supplementary exercise dose based on health condition within the intervention group. To calculate supplementary exercise dose per day the total time and repetitions performed using the app was divided by an adjusted LOS. LOS was adjusted in this analysis (calculated by actual LOS minus two days) to reflect the time required for recruitment and app set-up. Simple scatterplots were created to assess for outliers. Statistical significance for all tests was set at $p < 0.05$.

Results

Participants

The flow of participants is presented in Figure 1. A total of 147 participants were identified for the research project during the study period. After removing three participants not meeting our inclusion criteria, a total of 144 eligible participants were included in the study. Demographic information and baseline measures for the participants can be found in Table 1. There were no significant differences between the two groups at baseline.

Four participants were excluded from outcome data analyses. One participant was excluded due to transfer to acute care. Two participants withdrew as they were concerned that they could not complete the app exercises. The remaining participant withdrew because of feeling pressured to perform additional exercise. Our outcome analyses included 140 participants including 71 participants in the intervention group and 69 participants in the control group (Figure 1).

Effect of intervention on functional outcomes

Table 2 presents data on functional outcomes pre- and post-intervention for both the control and intervention groups. Both the control and intervention groups demonstrated significant differences for all functional outcome measures when comparing pre- and post-intervention measures ($p < 0.001$). There were no significant differences in post-intervention outcome measures between the two groups.

Table 3 presents change in functional outcome measures between control and intervention groups. There were no significant differences between the groups in terms of primary outcome measures as measured by walking speed (10mWT) and disability (FIM). Furthermore, the secondary measures of walking endurance (6MWT) and functional mobility (TUG) also demonstrated no difference.

Effect of intervention based on health condition

Table 4 shows change in functional outcome measures of control and intervention groups based on health condition. There were no significant differences in any of the major outcome measures when sub-group analysis based on health condition was performed.

Adherence to the intervention

Table 5 presents data on the supplementary exercise performed by the intervention group. There were not statistically significant differences in daily supplementary exercise dose (repetitions and duration) based on participants' health conditions. However, those admitted with an orthopaedic diagnosis completed more repetitions of supplementary exercise per day (55 repetitions per day, SD 51) compared to those who presented with a neurological diagnosis or for reconditioning purposes (40 repetitions per day, SD 40 and 39 repetitions per day, SD 49 respectively). The orthopaedic population also spent more time completing supplementary exercise (9 min per day, SD 11) compared to the neurological and reconditioning populations (6 min per day, SD 6 and 4 min per day, SD 5 respectively).

Discussion

Our study is one of the first to investigate the effect of an mHealth intervention targeting supplemental exercise in a rehabilitation setting. The results demonstrated no added benefit of an app-based supplemental exercise program in addition to usual care physiotherapy on functional outcomes in a rehabilitation setting. Intervention participants completed an additional seven minutes of exercise per day in this current study. Those admitted with an orthopaedic diagnosis showed greatest uptake of the app, completing an additional nine minutes and 55 repetitions of exercise per day. Participants with other health conditions (neurological and reconditioning) also utilised the app, although this was limited. The use of an app-based exercise program only provided a small increase in independent exercise dose for population groups common to rehabilitation settings. Moreover, use of such an app varies based on the user's health condition.

The findings of this study are similar to others which have examined the use of technological interventions for physical activity promotion in the general population. Research in this area

currently offers equivocal evidence and most studies have been conducted in the short-term.²⁵ Our study, too, was conducted in the short-term and did not offer longer-term follow-up. A recent study which tracked participants' behaviour with use of three fitness apps over a five-month period found a high drop off in behaviour after the first month.²⁶ Interestingly, maximal average use in the first month was only 56 minutes.²⁶ Similarly, in our study, the participants' utility of the Pt Pal app could be considered low and also diminished over time. The intervention led to a slight increase in the amount of physical activity performed, however did not affect physical function.

The additional seven minutes of daily supplementary exercise in the intervention group was well below what the research team had planned. The limited uptake of the app may be explained by a number of factors. High levels of activity are already observed in this particular rehabilitation setting in contrast with most other similar settings.²⁷ Also, due to existing procedures and time restraints, there was suboptimal uptake of the Pt Pal™ app by the physiotherapists on site. This in turn, had an effect on when and how soon exercises were upgraded for participants, also potentially affecting participant usage and reducing motivation to use the app. This points to the need for buy-in of all stakeholders to ensure best use and effectiveness. In addition to this, factors such as technology anxiety and resistance to change, especially for older people, should be considered.^{28, 29} These were not specifically examined in our study but may be factors which deter older people from adopting mHealth.²⁸

There is minimal research specifically with regards to delivery of mHealth interventions in hospital or inpatient settings. However, successful components of interventions used on the general population may be applicable. Current research into the use of mHealth interventions for physical activity promotion in the general population suggests that those which incorporate behaviour change techniques (such as goal setting, self-monitoring of behaviour, social support, feedback on behaviour, prompts/cues and review of behaviour goals) have the greatest effect.^{25, 30, 31, 32} Integrating technologies has been recommended to increase the efficacy of mHealth interventions.^{33, 34, 35, 36} For example, a mHealth intervention with both tracking and texting components was able to increase physical activity but this effect was not observed when the tracking component was used alone.³⁴ Studies have also found that activity-monitoring devices can be used to increase habitual physical activity in the general population.^{37, 38, 39, 40} Such technologies are now readily available to the general public and have been established as an acceptable health promotion aid in the community.⁴⁰ Our chosen intervention focused on exercise delivery (intervention) but did not provide a means of self-monitoring or goal-setting (measurement) for the participant.

Strengths and weaknesses

Strengths of the study include that it was significantly powered and had a robust randomised controlled trial design. This trial was performed in an established sub-acute rehabilitation setting and the app was adopted by real clinicians and individuals in rehabilitation. The use of a novel technology is one of the main strengths of the study. As well as this, the results show that an app-based supplemental exercise program can be utilised by individuals in rehabilitation, even those in the older age range.

However, the study had several limitations. Firstly, there were technological barriers. The chosen app program, though able to perform its intended purpose, had mediocre graphics and limited customisability. Feedback from the pilot study suggested that graphics were poor. In an attempt to minimise this barrier, members of the research team photographed certain exercises and uploaded these images onto the app for this RCT. The app was rigid from both the clinician and user end in some respects. For example, the app required speed to be set for each exercise and constant prompts were dictated during use but this increased clinician set-up time and did not allow for real time adjustments by the participant which may

have reduced motivation. Exercises could only be recorded if the app program was opened and exercise routine started thus exercises were not recorded if participants completed them without using the app.

Secondly, the intervention was used in the short-term and no longer-term follow-up was provided. As rehabilitation participants already receive therapy, use of such a program after the sub-acute period for the purpose of guiding activity in the community may be of greater benefit to this population. Interestingly, it was observed that app usage decreased over the participant's admission. This likely reflects the initial excitement of using a novel technology and reduced motivation to use the technology once trialled.

Lastly, current research points to a multi-faceted approach for mHealth physical activity interventions, however, our intervention was solely focussed on exercise delivery. The chosen app did not provide other components such as self-monitoring or an element of reward which may affect uptake.

Implications

Further research on physical activity promotion is indicated in the developing field of mHealth, specifically to examine methods of delivery which are most effective in hospital or rehabilitation settings. A supplemental exercise program can offer added benefit such as extra time being active and offer monitoring of progress. Consideration should be taken into the role of such a program in addition to usual care and methods of integrating this technology to booster clinician and user acceptability. The type of app and its delivery; the clinical setting whether in an acute ward, subacute facility or outpatient community; as well as whether it is a unimodal or multi-modal intervention are factors to its effectiveness. Each stakeholder should be optimised including consideration of appropriate population groups and clinician buy-in.

Conclusion

An app-based exercise program can facilitate a small supplementary exercise dose in a rehabilitation setting. However, the addition of an app-based exercise program in rehabilitation does not affect functional outcomes when compared to usual care.

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Table 1. Baseline characteristics of participants in the control and intervention groups

Characteristic	Control (N = 71)	Intervention (N = 73)	<i>p</i>
Age, mean (SD)	66 (13)	65 (12)	0.906
Gender, female, N (%)	40 (56%)	41 (56%)	0.983
Condition, N (%)			0.723
Orthopaedic	44 (62%)	44 (60%)	
Neurological	16 (23%)	22 (30%)	
Reconditioning	11 (15%)	7 (10%)	
Number of comorbidities, mean (SD)	4 (2)	4 (2)	0.340
MMSE, mean (SD)*	29 (1)	28 (2)	0.686
FIM Motor Score on admission, mean (SD)	79 (7)	78 (6)	0.647
FIM Cognition Score on admission, mean (SD)	21 (4)	21 (3)	0.626
Length of stay (days), mean (SD)	14 (8)	15 (9)	0.723

MMSE = Mini-Mental State Exam; FIM = Functional Independence Measure

*Available among 64 cases in control group and 66 cases in intervention group

Table 2. Functional outcome measures pre- and post-intervention

Outcome	Control					Intervention				
	Pre		Post		<i>p</i>	Pre		Post		<i>p</i>
	N	Mean (SD)	N	Mean (SD)		N	Mean (SD)	N	Mean (SD)	
Walking speed (m/s)	62	0.7 (0.3)	62	1.0 (0.4)	<0.001	67	0.7 (0.4)	67	1.1 (0.5)	<0.001
FIM	69	99.3 (10)	69	117.5 (10)	<0.001	71	99.1 (9)	71	118.2 (8)	<0.001
6MWT, distance (m)	59	204.0 (111.2)	59	302.5 (120.3)	<0.001	67	201.8 (117.8)	67	312.2 (134.2)	<0.001
TUG, time (s)	52	24.0 (20.1)	52	14.0 (8.5)	<0.001	60	27.1 (27.4)	60	14.4 (12.0)	<0.001

10mWT = 10 Metre Walk Test; FIM = Functional Independence Measure; 6MWT = 6 Minute Walk Test; TUG = Timed Up and Go

Table 3. Change in functional outcome measures

Outcome	Control Mean (SD)	Intervention Mean (SD)	Between groups mean difference (95% CI)
Walking speed (m/s)	0.3 (0.3)	0.4 (0.3)	-0.1 (-0.2 to 0.0) <i>p</i> = 0.157
FIM	18 (10)	19 (6)	-0.9 (-3.6 to 1.8) <i>p</i> = 0.519
6MWT, distance (m)	98.4 (68.2)	110.4 (75.6)	-12.0 (-37.5 to 13.5) <i>p</i> = 0.354
TUG, time (s)	-10.0 (13.4)	-12.6 (18.6)	2.6 (-3.5 to 8.8) <i>p</i> = 0.400

10mWT = 10 Metre Walk Test; FIM = Functional Independence Measure; 6MWT = 6 Minute Walk Test; TUG = Timed Up and Go

Table 4. Change in functional outcome measures between pre- and post-intervention across health conditions

Outcome	Ortho					Neuro					Reconditioning				
	Control		Intervention		Between groups mean difference (95% CI)	Control		Intervention		Between groups mean difference (95% CI)	Control		Intervention		Between groups mean difference (95% CI)
	N	Mean (SD)	N	Mean (SD)		N	Mean (SD)	N	Mean (SD)		N	Mean (SD)	N	Mean (SD)	
Walking speed (m/s)	42	0.4 (0.3)	40	0.4 (0.3)	0.0 (-0.2 to 0.1) <i>p</i> = 0.562	11	0.2 (0.3)	20	0.4 (0.4)	-0.2 (-0.4 to 0.1) <i>p</i> = 0.191	9	0.3 (0.3)	7	0.4 (0.2)	-0.1 (-0.4 to 0.2) <i>p</i> = 0.376
FIM	43	18 (6)	42	17 (5)	0.7 (-1.8 to 3.1) <i>p</i> = 0.588	16	17 (16)	22	22 (8)	-5.2 (-13.3 to 2.9) <i>p</i> = 0.205	10	21 (7)	7	19 (5)	1.3 (-5.2 to 7.8) <i>p</i> = 0.672
6MWT, distance (m)	38	103.3 (64.2)	40	115.6 (78.6)	-12.3 (-44.8 to 20.1) <i>p</i> = 0.451	13	85.7 (83.3)	20	105.6 (75.4)	-19.9 (-77.0 to 37.1) <i>p</i> = 0.482	8	96.3 (67.2)	7	94.7 (64.6)	1.6 (-72.3 to 75.4) <i>p</i> = 0.964
TUG, time (s)	35	-11.7 (15.8)	35	-14.0 (18.5)	2.3 (-5.9 to 10.5) <i>p</i> = 0.574	9	-6.4 (4.5)	19	-11.5 (21.5)	5.2 (-9.8 to 20.1) <i>p</i> = 0.486	8	-6.7 (5.5)	6	-8.1 (7.8)	1.4 (-6.4 to 9.2) <i>p</i> = 0.702

10mWT = 10 Metre Walk Test; FIM = Functional Independence Measure; 6MWT = 6 Minute Walk Test; TUG = Timed Up and Go

Table 5. Supplementary exercise data in the intervention group

Outcome	N	Mean (SD)
Total number of repetitions of supplementary exercise performed	71	552 (598)
Repetitions of supplementary exercise performed per day (reps/d)	71	49 (48)
Total duration of supplementary exercise (min)	70	80 (99)
Duration of supplementary exercise per day (min/d)	70	7 (9)

Figure 1. Flow of participants through the trial, n=140

