JRM-CC
JOURNAL OF REHABILITATION MEDICINE CLINICAL COMMUNICATIONS
VOL. 5, 2022 ARTICLE 1000076

ORIGINAL REPORT

INCLUDING EXERCISE SELF-MANAGEMENT AS PART OF INPATIENT REHABILITATION IS FEASIBLE, SAFE AND EFFECTIVE FOR PATIENTS WITH COGNITIVE IMPAIRMENT

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Objective: **To test the feasibility, safety and effectiveness of the My Therapy programme for inpatients with mild-moderate cognitive impairment.**
Design: **Observational pilot study.**
Patients: **Rehabilitation inpatients with mild-moderate cognitive impairment.**
Methods: **During their inpatient admission, participants received My Therapy, a programme that can increase the dose of rehabilitation through independent self-practice of exercises, outside of supervised therapy. Outcomes included My Therapy participation, falls, Functional Independence Measure (FIM) and 10-m walk test. Outcomes were compared with those of participants without cognitive impairment from the original My Therapy study ($n = 116$) using $\chi 2$ and independent *t*-tests.**
Results: **Eight participants with mild-moderate cognitive impairment (mean (standard deviation (SD)) age 89.6 years (4.8); 3 women) were included. All participants completed the My Therapy programme on at least one day of their admission, with no associated falls. Participants had an 8.4 s (SD 5.1) reduction in their 10-m walk test and a 21.5 point (SD 11.1) improvement on FIM scores from admission to discharge. There were no significant between-group differences in feasibility, safety or effectiveness for participants with and without cognitive impairment.**
Conclusion: **This pilot study has shown that including exercise self-management as part of inpatient rehabilitation is feasible, safe and effective for patients with cognitive impairment.**

LAY ABSTRACT

This study aimed to determine whether it was practical, safe and effective for patients in a rehabilitation hospital with memory or thinking problems to participate in a programme called My Therapy. My Therapy aimed to increase the dose of rehabilitation through independent self-practice of exercises, outside of supervised therapy sessions. There were 8 participants in the study and all of them reported completing the My Therapy programme on at least one day of their rehabilitation stay. There were no falls relating to My Therapy participation. Participants improved their walking speed and function during their rehabilitation stay. There were no differences in the results between people with and without memory or thinking problems, in terms of practicality, safety or effectiveness. This study has shown that including exercise self-management as part of rehabilitation is practical, safe and effective for patients with memory or thinking problems.

Key words: hospital; rehabilitation; self-management; cognitive impairment; feasibility; safety.

Accepted Nov 9, 2021; Published Jan 13, 2022

JRM-CC 2022; 5: jrmcc00076

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Foundation of Rehabilitation Information
doi: 10.2340/20030711-1000076

JRM–CC

Cognitive impairment can be viewed as a barrier to participation in clinical trials, with over 80% of non-cognitive specific trials excluding adults who lacked cognitive capacity (1, 2). The rational for exclusion from clinical trials includes a real or perceived inability to consent, follow instructions or report outcomes (1), in addition to safety concerns. Cognitive impairment can also be viewed as a barrier to engagement in inpatient physical rehabilitation (3), despite the reported benefits for patients across the full spectrum of cognition (4). Inpatient rehabilitation may include therapy delivered in one-on-one supervised sessions or group sessions. Patients may also be encouraged to participate in exercise self-management, due to the known benefits of increased exercise participation for quality of life and function (5).

While most research on exercise self-management is conducted in community settings and focuses on chronic health conditions, 2 recent studies have shown it is feasible and safe to introduce a self-management programme, focussed on independent exercise practice, to the inpatient rehabilitation setting (6, 7). These 2 studies included patients with traumatic brain injury (7), and musculoskeletal conditions and frailty (6), the latter evaluating the self-management programme, My Therapy.

My Therapy is an inpatient rehabilitation self-management programme, which can increase the dose of therapy participation through independent self-practice of exercises outside of supervised therapy sessions (6). In previous pilot research, participation in My Therapy led to participants completing 100 additional min per week of practice alongside usual care rehabilitation, without additional staffing resources, adverse events or safety concerns. However, similar to other clinical trials (2), patients with cognitive impairment were excluded (6). The primary aim of the current study was to determine the feasibility, safety and effectiveness of participating in My Therapy for patients with a cognitive impairment. The secondary aim was to compare these outcomes with those of patients without cognitive impairment, included in the original My Therapy pilot study (6) .

METHODS

Participants

This study aimed to recruit patients admitted to inpatient rehabilitation with frailty or musculoskeletal conditions, on 1 of 2 rehabilitation wards at the participating health service. Patients were included if they were 18 years or older and had a documented cognitive impairment, corresponding to a score of 25 or less on the Montreal Cognitive Assessment (MoCA) (8). Informed consent was obtained from the patient, and/or from the next of kin in case of a moderate or severe cognitive impairment. Data from this study were compared with those collected from participants without a cognitive impairment from the original My Therapy pilot study (6). Ethics approval was provided by the Cabrini Human Research Ethics Committee (CHREC 06-18-01-16).

Procedures

My Therapy has been previously described in detail (6). My Therapy aimed to encourage and educate the patient and, if required, their caregivers, to complete an independent therapy programme. The programme was developed in collaboration with patients and included a sub-set of routine therapy tasks and exercises recommended by the treating occupational therapist and physiotherapist. The programme was delivered via a booklet and could be completed at any time the patient chose. Families were engaged in the My Therapy programme, with the role of encouraging patients to complete their self-practice. Additional safety precautions were taken for patients with a cognitive impairment, including: (*i*) an acknowledgement that some patients may not be ready for My Therapy at the start of their admission and could start when safe to do so; (*ii*) starting with a small number of activities and building up; and (*iii*) if required, limiting exercises or tasks to the bed or chair.

Data collection

The treating physiotherapist or occupational therapist collected demographic data, including age, sex and cognitive score from the medical record. Usual care occupational therapy and physiotherapy daily participation time were also collected by therapists, to understand baseline therapy participation.

Feasibility was measured as the percentage of participants completing My Therapy on one or more days during the rehabilitation admission, and the amount of My Therapy participation time. To collect these data, patients and families were asked by the treating therapists to record daily adherence to the programme in the My Therapy booklet, including the time taken to complete the tasks and exercises. Safety was measured as falls occurring during the inpatient stay, both with and without an injury. Falls data were collected by the research team from the patient medical record and the hospital's electronic adverse events system. Programme effectiveness was measured via the 10-m walk test (where less time indicated a better outcome), the Functional Independence Measure (FIM) (where a higher score indicated a better outcome), and the percentage of participants achieving a minimum clinically important difference (MCID) in FIM score (22 points) (9). These data were collected on admission and discharge by the treating physiotherapist or occupational therapist.

Statistical analysis

Continuous data were reported as means and standard deviations and categorical data were presented as frequencies and percentages. Feasibility, safety and effectiveness were compared between participants with and without cognitive impairment using χ^2 and independent *t*-tests. SPSS software was used for all analyses (IBM Corp. Released 2017. IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp) and significance was set at $p<0.05$.

RESULTS

Participants

Between September 2019 and January 2020, 10 participants were recruited. Of the 10, 8 were included in the analysis as 1 participant was readmitted to acute care due to medical issues (unrelated to My Therapy participation) and 1 lost their My Therapy booklet prior to discharge and

Table I. Participant characteristics and participation in usual care therapy

Characteristica	Participants with cognitive impairment ($n=8$) Mean (SD)	Participants without cognitive impairment ($n=116$) Mean (SD)
Age, years, *n*	89.6 (4.8)	79 (9.9)
Female, *n* (%)	3 (38)	75 (65)
Cognition*	19.3 (3.9)	No cognitive impairment
Pre-admission accommodation, *n* (%)		
Home	7 (88)	115 (99)
Residential care	1 (13)	1 (1)
Discharge accommodation, *n* (%)		
Home	6 (75)	100 (86)
Residential care	1 (13)	4 (3)
Respite care	1 (13)	0 (0)
Hospital transfer	0 (0)	12 (10)
Length of stay, days	23.8 (9.2)	11.9 (5.4)
Usual care occupational therapy participation, min		
Per admission	852.1 (365.3)	860.3 (546.5)
Per day	37.2 (17.3)	73.6 (34.7)
Usual care physiotherapy participation, mins		
Per admission	1,705.7 (365.6)	1,020.8 (395.6)
Per day	76.8 (24.5)	89.8 (23.2)

*Scores range from 0 to 30: higher score reflects higher cognitive state (8).

therefore did not have data to contribute to the analysis. Cognition scores ranged from 13 to 24, indicating mild to moderate cognitive impairment. Seven participants (88%) were living at home prior to admission (**Table I**). The mean (SD) length of stay was 23.8 days (SD 9.2). Participants without cognitive impairment group from the original study ($n=116$) were younger, more commonly female and had a shorter mean length of stay (Table I).

Feasibility and time spent participating in My Therapy

Therapists initially recommended between one ($n=7$, 87.5%) and 3 ($n=1$, 12.5%) sets of My Therapy tasks and exercise per day, with this number modified, as clinically indicated, during admission. One hundred percent of participants reported completing the programme on at least one day of their admission (**Table II**). Participants reported completing the programme on 23.0% of days admitted (range 4.2–84.2%), with an mean participation time of 137.3 min (SD 149.0) throughout their admission or 6.8 min (SD 7.9) per day (Table II).

In comparison, 72% of participants without cognitive impairment from the original pilot study reported completing the programme on at least one day ($p=0.078$) (Table II). Participants without cognitive impairment group had a higher mean participation time than participants with cognitive impairment of 158.8 min (SD 175.6) throughout their admission, or 14.0 min (SD 14.2) per day, although these differences were not significant.

Safety of participating in My Therapy

There were no falls reported for any participants throughout the study. There were also no reported occasions of participants unsafely exceeding the prescribed level of tasks or exercises, e.g. completing a sitting exercise in standing. These results were consistent with those from the original pilot study in participants without cognitive impairment.

Table II. Feasibility and effectiveness (mobility, function) of My Therapy participation for participants with and without cognitive impairment

Outcome	Participants with cognitive impairment ($n=8$) Mean (SD)	Participants without cognitive impairment ($n=116$) Mean (SD)	*p*-value
Participation in My Therapy on at least one day, *n* (%)	8 (100)	83 (72)	0.078
My Therapy participation time (min)			
Per admission	137.3 (149.0)	158.8 (175.6)	0.736
Per day	6.8 (7.9)	14.0 (14.2)	0.160
10-m walk speed (s)			
Admission	23.2 (7.3)	18.9 (13.3)	0.368
Discharge	14.7 (4.8)	13.9 (8.9)	0.802
Change	–8.4 (5.1)	–5.0 (8.2)	0.250
Total FIM score			
Admission	81.6 (11.1)	94.4 (8.9)	<0.001
Discharge	103.1 (8.5)	104.6 (26.6)	0.874
Change	21.5 (11.1)	10.3 (24.1)	0.196
Achieving MCID in function, *n* (%)	3 (37.5)	26 (22.4)	0.330

*Scores range from 7 to 126: higher score reflects higher function (9) FIM: Functional Independence Measure; MCID: minimal clinically important difference = +22 FIM points.

Effectiveness of My Therapy

Participants with cognitive impairment had an 8.4 s (SD 5.1) reduction in their 10-m walk test and a 21.5 point (SD 11.1) improvement on their FIM score from admission to discharge (Table II). In comparison, participants without cognitive impairment had a 5.0 s (SD 8.2) reduction in their 10-m walk test and a 10.3 point (SD 24.1) improvement on their FIM score from admission to discharge. Three participants with cognitive impairment (37.5%) achieved an MCID in function, compared with 26 participants without cognitive impairment (22.4%) ($p=0.330$) (Table II). Participants with cognitive impairment had significantly lower admission FIM scores than participants without cognitive impairment ($p<0.001$). There were no other significant differences between groups.

DISCUSSION

This observational study demonstrated that it was feasible for people living with mild-moderate cognitive impairment to safely participate in My Therapy during inpatient rehabilitation, as was the case for people without a cognitive impairment. Participants with and without a cognitive impairment, also demonstrated gains in function and walking, with no significant between-group differences.

On admission, participants with a cognitive impairment had significantly lower FIM scores than participants without cognitive impairment. However, on discharge there was no difference in FIM scores, suggesting that participants with cognitive impairment had a greater improvement in function during their inpatient admission, than participants without cognitive impairment. Whether this was related to their participation in My Therapy is unknown.

Safety and engagement in self-practice were facilitated by implementing patient-oriented protocols and providing clear instructions from clinicians. Family members also played an important role in encouraging self-practice, particularly for those patients with mild-moderate cognitive impairment. These findings suggest that cognitive impairment is not necessarily a barrier to participating in an exercise self-management programme and supports participation in future My Therapy clinical trials. The extent to which these findings apply to people with severe cognitive impairment awaits confirmation.

Caution must be taken when interpreting these observed results due to the small number of participants with a cognitive impairment. For this cohort, there was potential for over or under-reporting of My Therapy participation due to the reliance on self-report for this outcome. In addition, this study only included participants admitted to rehabilitation with frailty or musculoskeletal conditions, limiting generalizability to the wider rehabilitation population. Research currently underway will address these limitations through a fully funded, multi-site randomized controlled study of My Therapy, which is inclusive of people with a cognitive impairment (10). This study provides an example of how a pilot study, focused on people with a cognitive impairment, promoted a more cognitively inclusive approach to a future clinical trial in rehabilitation (10).

ACKNOWLEDGEMENTS

The authors would like to acknowledge and thanks the patients and staff who participated in the questionnaire and in the My Therapy programme. In addition, the authors would like to acknowledge Cabrini Health for the in-kind support that was given to this study.

The authors have no conflicts of interest to declare.

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