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Research article

Integrating research into clinical practice for hip fracture rehabilitation: Implementation of a pragmatic RCT

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Abstract: *Objective:* Testing clinical interventions integrated within health care delivery systems provides advantages, but it is important to make the distinction between the design of the intervention and the operational elements required for effective implementation. Thus, the objective of this study was to describe contextual factors for an outpatient follow-up clinic for older adults with hip fracture. *Design:* Implementation evaluation of a parallel-group 1:1 single-blinded two-arm pragmatic randomized controlled trial. *Setting:* Hospital-based multi-disciplinary outpatient clinic in Vancouver, Canada. *Participants:* Community-dwelling older adults (≥ 65 years) with hip fracture in the previous year. *Interventions:* Usual care vs. usual care and a comprehensive geriatric clinic for older adults after hip fracture. The primary outcome for the main study was mobility as measured by the Short Physical Performance Battery. *Outcome measures:* A description of central tenets of implementation that include recruitment, participant characteristics (reach) and aspects of the innovation (e.g., delivery system, fidelity to the intervention, and exercise dose delivered and enacted.

Results: We identified the reach for the intervention and delivered the intervention as intended. There were 53 older adults who enrolled in the study; more than 90% of participants returned for the final assessment. We provide a comprehensive description of the intervention and report on dose delivered to participants, and participants' 12-month maintenance for balance and strength exercises. *Conclusions:* It is important to move beyond solely assessing outcomes of an intervention and describe factors that influence effective implementation. This is essential if we are to replicate interventions across setting or populations or deliver interventions at broad scale to affect the health of patients, in future. *Trial registration:* This trial was registered on ClinicalTrials.gov (NCT01254942).

Keywords: process evaluation; older adults; hip fracture; implementation

1. Introduction

Hip fracture has a profound negative impact on older adults' everyday life. Although some physical activity (and specifically exercise) interventions enhance mobility post-fracture, results are not consistent. This may be a result of small sample sizes, diversity of interventions and (relatively) short follow-up periods [1]. Further, the wide variation in exercise interventions and outcomes measured prohibited pooling of data for meta-analyses [1] to discern an overall effect. Importantly, many studies do not report sufficient details of the intervention for future replication [2]. Consequently, there is insufficient clinical evidence, and even less information about program operations, to recommend a definite intervention or training protocol for older adults to recover mobility after hip fracture [1].

Implementation science is the *"scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services"* [3] (p1). Within the realm of implementation science, and to move research evidence into practice, it is imperative to simultaneously describe the: (i) target population (to ensure reach and generalizability of findings); (ii) clinical intervention in sufficient detail (for replication) [2]; (iii) essential research operational details needed to deliver the intervention and collect robust data. As implementation science continues to evolve, clinical research requires a strong interplay between guiding theory (and evidence), strong measurement principles (*rigor*) and practical application *(relevance)* to ensure alignment with patient-centered practice. Likewise, it is fundamental to understand how program elements are delivered, received, and adapted for implementation in different populations and settings [4,5].

Opportunities to implement what is learned from clinical research trials, to health care delivery systems is often inhibited by lack of clarity in reporting the design of an intervention and the operational elements deemed essential for effective implementation [2]. We identified several implementation and reporting challenges within the literature on rehabilitation interventions for older adults with hip fracture. First, there is frequently a lack of clear description of the target population to aptly determine generalizability of the intervention (e.g., external validity). Recruiting participants to test the efficacy (or effectiveness) of a trial present persistent challenges, especially when working with vulnerable older adults [6]. A multi-pronged recruitment approach is frequently used to

maximize recruitment. However, without a known sampling frame, outcomes may have systematic (non-observation) error [7,8], be non-generalizable (or applicable) and not reach the population of interest. Many studies use a convenience sample of participants. This limits researchers' ability to identify program reach and determine recruitment rate of the target population. This research design limitation potentiates the likelihood that the intervention will be tested in a non-representative sample. This, in turn, reduces generalizability to the larger clinical population.

Second, publications should include a well-defined description of the intervention (guided by tools such as Template for Intervention Description and replication (TIDieR) checklist [2]), and a framework for evaluating its implementation, including a statement of adopted behaviour change techniques (BCTs) [9]. However, these are seldom provided concurrently [10]. A recognized planning tool for implementation evaluation is RE-AIM (http://re-aim.org/) [11] which considers five elements related to the implementation of interventions including: Reach (target population), effectiveness (or efficacy), adoption (by setting/staff), implementation (dose delivered and received, fidelity to the intervention etc.) and maintenance of the behaviour (in target population and settings) [11]. It is essential to evaluate whether an intervention was implemented as planned (e.g., dose, fidelity), the effectiveness of the intervention (e.g., outcomes) and to discern the association between implementation and effectiveness to better interpret findings. For instance, if rehabilitation therapists delivered only part of a physical activity intervention (low fidelity), and if participants attend appointments only 30% of the time (low dose), the likelihood of a positive outcome diminishes. Hence, there is a need to differentiate between effects related to design of an intervention versus how it was implemented. To do so requires a description of implementation (Who was the target population and how was the intervention delivered, received and applied?) and outcome (did it work?) components [12].

In sum, there are several essential factors required to replicate a study, move an effective intervention into clinical practice, or distil the effects of an intervention program from its implementation. Thus far, these implementation factors have not consistently been described in previous publications on rehabilitation for older adults with hip fracture. Therefore, guided by Durlak and DuPre [12] and the RE-AIM evaluation framework [11,13], we describe participants who enrolled in study designed to test a hip fracture rehabilitation program, the rehabilitation intervention delivered, the process of operationalizing the intervention within a clinical setting, and participants' uptake of recommended clinical management.

2. Materials and methods

2.1. Study design and target population

We conducted a parallel-group 1:1 single-blinded two-arm pragmatic RCT to test the effect of usual care vs. usual care and a comprehensive geriatric clinic on mobility after hip fracture [ClinicalTrials.gov (NCT01254942)]. We worked with three academic teaching hospitals in Vancouver, Canada to recruit older adults with a recent (surgically repaired) hip fracture. We included community-dwelling older adults (65 years and older) with hip fracture who could walk at least 10 meters prior to the fracture; and did not have a diagnosis of dementia. This study was approved by university and hospital clinical research ethics board, and all participants provided written consent prior to participation. The study protocol is published elsewhere [14].

We used the Consolidated Standards of Reporting Trials (CONSORT 2010) Statement to design, conduct and report study findings [15]. Our primary outcome was mobility operationalized by the Short Physical Performance Battery (SPPB) [16]. We provide an overall description of the research and clinical components of the trial below. Table 1 provides a description of procedures for both groups based on the TIDieR checklist and guide [2].

2.2. Recruitment

We adopted three different recruitment strategies: (i) on-ward prior to discharge from hospital (or obtained permission while in hospital to contact potential participants after discharge); (ii) a letter of initial contact from health professional involved in the care following identification from hospital charts and/or discharge lists; (iii) through advertising in local healthcare centers, posters on ward, and word-of-mouth. For each mode, we recorded reasons for (non-) eligibility. After we identified eligible participants, the recruitment coordinator provided them with study information either in person or via mail. We telephoned participants and recorded reasons for declined enrollment.

2.3. Randomization

We randomly assigned all consenting participants to usual care or intervention groups by remote allocation. An independent statistician generated the allocation sequence using randomized blocks of varying size. This list was provided to a web-based randomization service. At the completion of baseline assessment, the project coordinator logged onto the system to determine the next allocation. If the participant was allocated to the intervention group, the project coordinator worked with the clinical service to set up an appointment with the geriatrician and other allied health care staff. Our protocol for all participants was to complete the baseline assessment, randomization and clinic visit (for intervention participants) within a two-week window.

2.4. Blinding

The project coordinator securely maintained the randomization outcome for all participants. Treatment allocation was concealed from the recruitment coordinator, and other members of the research team (e.g., research assistants, data entry personnel). Participants were aware of their treatment allocation as we were unable to blind participants to the type of post-fracture management received. During the in-person [with a physiotherapist (PT)] and telephone (with trained research assistants) data collection sessions, we requested participants not disclose their group allocation. The PT completed the primary outcome (SPPB [16]) first to minimize the chance that participants disclosed their group allocation before the collection of the primary measure.

2.5. Control arm

Participants randomized to the usual care group received usual orthopaedic post-operative treatment after hip fracture. This may have included a six-week follow-up appointment with the orthopaedic surgeon, home rehabilitation visits [PT, occupational therapist

(OT)] family physician visits, and/or visits to community-based PT. Participants allocated to this group were offered the intervention at 12 months (i.e., after they completed the final assessment).

2.6. Intervention arm

Participants who were randomized to the intervention group were offered an enhanced post-hip fracture follow-up clinic in addition to usual care. The clinical trial took place within an existing operational geriatric medicine clinic (i.e., not a stand-alone research clinic dedicated to research participant evaluations), with dedicated time slots for study participants. Prior to starting the research study, it was not common practice to refer older adults with hip fracture to this clinical service.

The B4 Clinic was a comprehensive geriatric assessment and management designed to assess falls and fracture risk factors. All intervention group participants were assessed by the same geriatrician, based on the guidelines established by the American and British Geriatrics Societies [17]. Participants were also assessed by a PT and OT via outpatient appointments. The number and content of appointments were determined by the clinicians based on the needs and goals of each participant. Our main research focus was on the return of mobility, and therefore in this paper we report implementation factors related to mobility, including physical activity. However, as per a comprehensive geriatric management plan, physical activity was only one element of the clinical focus.

2.7. Implementation

As part of our formative evaluation for the larger trial, we conducted a pilot study to test our recruitment strategies, research operational processes, data collection protocols (content and timing) [18] and confirmed *adoption* of the "Clinic" by one hospital site. We used this information to train staff and "test run" our study manual of procedures and standard operation procedures (SOP), in advance. During both the pilot study and main trial, the project coordinator maintained detailed logs to monitor implementation of the study protocol (*fidelity to research protocols*). We conducted brief telephone-based semi-structured interviews (at 6 and 12 months) with study participants to identify why they joined the study, acceptability of the intervention and research, health related goals [19] and overall perspectives on the recovery process [20]. Adherence to the Clinic (*fidelity and dose*) was monitored by a chart review at 12 months conducted by a trained research assistant (for participants in the intervention group). For all participants, health professional visits (*dose*) were monitored using monthly self-report measures (via telephone interviews with trained research assistants). Adherence to strength and balance exercises (*dose*) was captured by the self-report physical activity questionnaire [Community Healthy Activities Model Program for Seniors (CHAMPS)] [21]. The CHAMPS questionnaire was administered monthly via telephone by trained research assistants, and the following items represented strength and balance activities at baseline, midpoint or final assessment: Stretching or flexibility; yoga or tai chi; general conditioning; light strength training and/or moderate to heavy strength training [21]. We also provide a description of BCTs adopted during health care visits using a standard behaviour change taxonomy, called BCTTv1 [9] (Table 2). This taxonomy is a tool for users to systematically identify the content of interventions in 93 distinct BCTs clustered into 16 categories [9]. We report on two health behaviours; physical activity (e.g., exercise, activities of daily living, etc.) and health resource utilization (e.g., physician and allied health appointments).

Table 1. Description of procedures for both groups based on the Template for intervention description and replication (TIDieR) checklist and guide [2].

Name	B4 (Balance, Bone, Brain and Bladder) post-hip fracture clinic for older adults
Rationale	Despite advances in surgical techniques and medical care for hip fracture, there remains excess risk for mortality [43], and loss of mobility [44], with older adults facing further risks of falls, fractures and loss of independence. The aim of the B4 clinic was to provide comprehensive geriatric management for older adults post-hip fracture.
Materials Provided Intervention	The intervention group participants may have received a copy of the 5 Fav exercises developed in consultation with a physiotherapist (PT). The exercises included: Sit to stand practice, standing sway (limits of balance), light marching on the spot (hip flexion), lifting leg to the side (hip abduction) and lifting leg to the back (hip extension). Written instructions reminded participants to have a sturdy surface nearby for support for standing/balance activities. A registered PT (aware of appropriate chair height and hip precautions) provided the exercise sheet.
Research and other	For both groups, we sent a letter (after obtaining participant permission) to family physicians alerting them to the fact that their patient was enrolled in the trial. At the end of the study, we provided participants with a summary of selected health measures for the three-time points. On request from participants, we provided general information on community resources for caregivers. We sent all participants holiday and birthday cards.
Procedures	This was a parallel-group 1:1 single-blinded two-arm pragmatic randomized controlled trial comparing usual care to a post-hip fracture outpatient clinic (and usual care). The design, conduct, analysis and reporting of this clinical trial conformed to published guidelines in the Consolidated Standards of Reporting Trials (CONSORT 2010) [15].

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Name	B4 (Balance, Bone, Brain and Bladder) post-hip fracture clinic for older adults	
Clinical	*Intervention* Participants received usual care for hip fracture in the acute and community setting. ---------- All intervention participants also attended an outpatient comprehensive geriatric clinic for hip fracture for assessment by a geriatrician, an occupational therapist (OT), and PT following guidelines established by the American and British geriatric societies [45]. This included a review of falls, fractures, their circumstances and risk factors, hospitalization, other health conditions, nutrition, medications, activities of daily living, function, mobility status, mobility aids, current exercise practice, living arrangements, social supports, patient report of their home environment, fear of falling, activities cut back on due to mobility, actions taken to reduce falls, and treatment goals. Clinic measurements included a complete physical examination including BMI and blood pressure (supine and standing), gait evaluation, cognitive testing, and depression screen. The number and content of investigations, treatments and follow-up visits were determined by the clinicians and participants' preference based on their needs and goals. The OT provided further follow-up and assessment for participants with cognitive concerns around memory and other cognitive function strategies including goal setting and energy conservation, as well as providing further assessment and management (cognitive behavioural therapy, sleep hygiene, relaxation techniques) of those with sleep impairment and in advance of any planned sedative taper by the geriatrician. The PT measured lower extremity strength and balance, evaluated gait on an electronic walkway, screened for vestibular dysfunction contributing to balance impairment and offered vestibular rehabilitation exercises as needed in addition to postural, balance, gait and strength exercise prescription. Clinic attendees may have attended weekly balance exercise groups led by a rehab assistant after initial sessions with the PT. Participants also had access to a registered dietician and a continence nurse in the clinic on referral by the geriatrician.	*Usual care* Participants received usual care for hip fracture in the acute and community setting.
Research	A registered PT, blinded to group allocation, assessed all study participants in-person three times: Baseline, midpoint (6 months) and final (12 months). Additionally, trained research assistants collected monthly information (via the telephone) related to adverse events (including falls), health resource utilization, quality of life, and physical activity. At 6 and 12 months, the project coordinator conducted semi-structured interviews with participants to document health and life goals and asked for their feedback on their recovery, the intervention and the research project.	

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Name	B4 (Balance, Bone, Brain and Bladder) post-hip fracture clinic for older adults	
Research staff training	We provided detailed training to research staff on communication with participants, research ethics, and data collection. Research assistants completed ethics training via an online course (2–3 hours in duration) and all staff signed a confidentiality form to undertake research. Research staff read the study protocol, B4 Clinic Study manual of procedures and received training on its content and application. Upon completion of training, research staff signed the training log. The project coordinator ensured all research staff completed the necessary training and that the training log was up to date.	
Clinical Providers	*Intervention* Usual health care providers for management after hip fracture (e.g., possible visits with family physician, PT). --- At the Clinic, all participants were assessed by the geriatrician, PT, and OT. Some participants were seen by a continence nurse, dietician and social worker.	*Usual care* Usual health care providers for management after hip fracture (e.g., possible visits with family physician, PT).
Research Providers	The project coordinator was responsible for contact with all participants and was the liaison with the Clinic. There was one main research PT who conducted 125 (79%) of the assessments, and a second registered PT who completed the remaining assessments. Both research PTs reviewed the protocols and one PT trained the other. There were several trained research assistants who made the monthly phone calls.	
Research location(s)	Participant assessments took place in participants' home or at our research centre (depending on the preference of participants). Research assistants' and the project coordinator's telephone calls were completed from our Centre.	
Participant Adherence to research	*Strategies to maximize adherence:* Every effort was made to retain study participants without coercion. During enrollment, we obtained ethics and participants' permission to collect the names and contact information for several individuals closely related to the participant (e.g., next of kin, friends, etc.). Such individuals were only contacted in the event that a confirmed appointment was not kept or if multiple attempts to reach a participant by telephone were unsuccessful. We organized B4 related appointments and some transportation for the participants. In addition, as pain and fatigue were an issue for some participants early after the hip fracture, we collected all research data at home or on the phone (depending on the request of the participant). However, as part of the Clinic, the geriatrician and other health professionals were located at the hospital site, and this may have influenced intervention participants' attendance at health professional appointments. A priori, our strategy and plans for participant retention also included: Monthly phone calls, birthday and holiday cards. We attempted wherever possible to address other barriers, including participants with low English language communication proficiency, and age-related sensory losses in vision and hearing.	

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Name	B4 (Balance, Bone, Brain and Bladder) post-hip fracture clinic for older adults
Data Collection, Entry, and Screening	Data were collected by trained research PTs or research assistants. Our target was to collect data within two weeks of the actual date (calculated from baseline assessment). This included arranging the baseline assessment within a window of two weeks of scheduling the Clinic assessment (in the event that the participant was allocated to the intervention group). Following data collection, the project coordinator checked it for completeness, and followed-up if data were missing. The receipt of data was entered into the master log. The data (with no identifying information) were entered twice by an independent company. When the electronic files were received by the project coordinator, 10% of all data were checked for accuracy. If there were any discrepancies, then all data were checked against the original documents. The project coordinator also completed data cleaning and screening and logged all changes in the Data Cleaning Log. The project coordinator ran preliminary exploratory statistics on all data entered to search for data entry errors and outliers, computed simple descriptive analysis and developed tables for data display.
Intervention Location, Mode and Frequency of Delivery	The Clinic was located at one academic teaching hospital in Vancouver, Canada. One geriatrician conducted all intervention clinical assessments at the hospital (approximately 90 minutes duration). The clinical assessments focused on four key areas to address secondary prevention of fracture: Bone health, bladder function, balance and brain function. The PT and OT also assessed each intervention participant at the Clinic (30 minutes each). The duration of subsequent appointments depended on the participants' needs and clinical judgement. The geriatrician made referrals to other physicians and health professions as needed. These additional health professional appointments occurred either at the hospital or medical offices, and the frequency was based on participants' needs. Some participants were also provided with a home program to complete independently.
Frequency and Volume	All intervention participants received at least one assessment by the geriatrician, PT and OT. Participants received additional appointments and/or referrals as needed. Please see below (*Number of contact sessions*) for more details.
Tailoring	The intervention delivered to participants was tailored to their specific health needs following hip fracture.
Behaviour Change Techniques (BCTs)	Table 2 provides an overview of BCTs that participants received with their interactions with the Clinic health professionals for physical activity and health care/resource utilization. Further, we acknowledge that the monthly telephone calls delivered to both may have been a co-intervention by providing social support (unspecified and emotional) to study participants.
Modifications to Protocol	(i) Not all participants received the 5 Fav exercise handout. (ii) We plan to provide four additional telephone calls based on motivational interviewing [46] for intervention participants following discharge from the clinic. These were intended to work with participants to problem solve and facilitate goal setting around mobility and regular engagement in physical activity. We did not do this to reduce burden as we were already calling them monthly and they were encouraged to contact us if there were any adverse events to report.

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Name	B4 (Balance, Bone, Brain and Bladder) post-hip fracture clinic for older adults	
Delivery	All Clinic health professional visits occurred at the hospital.	
Implementation		
Number of contact sessions by group allocation (intervention group only) *calculated by Clinic chart review*	All intervention participants received at least one assessment by the geriatrician, PT and OT, and additional appointments and/or referrals as needed. The median (10, 90) number of visits to the: Geriatrician was 2 (1, 4); PT was 2 (1, 11.6); OT was 1 (1, 4.3). The geriatrician made referrals to other health professionals (within the hospital): Continence nurse (n = 3 participants); dietician (n = 2 participants); social worker (n = 1 participant). Four participants (15%) continued with their Clinic PT program after trial completion.	
Number of PT and OT visits by both groups (outside of intervention) *calculated by prospective monthly telephone interviews*	*Intervention* Participants reported 0–59 PT sessions over 12 months, median (10, 90) was 1 (0, 21.7); there were four participants who had more than 12 visits. Only five OT sessions were reported (one each for n = 5).	*Usual care* Participants reported 0–80 PT sessions over 12 months, median (10, 90) was 1 (0, 26); there were three participants who had more than 12 PT visits. No OT sessions were reported.
Participant Adherence to Intervention	All participants attended the Clinic and were assessed by the geriatrician, PT and OT. We are not able provide specific details on participants' adherence to their tailored physical activity program.	
Participant adherence to self-reporting strength or balance exercises using selected questions from CHAMPS [21]*	At 12 months 18/25 (72%) of participants in the intervention and 10/25 (40%) of participants in the control group self-reported engaging in strength or balance activities (for a typical week over the previous month).	

*CHAMPS = Community Healthy Activities Model Program for Seniors. We extend the TIDieR checklist to provide detailed operational information that supports replication of our intervention, in future. All participants (from both intervention and control groups) were: (1) assessed at three-time points (baseline, 6 and 12 months) by a registered PT; (2) received a monthly telephone call to collect information on any adverse events, health resource utilization and/or quality of life measures.

Table 2. Behaviour change techniques (BCTs) used in the intervention and research process over the course of the clinical trial [9,47].

Behaviour Change Technique	Intervention Group	Control Group
Goals and planning		
Goal-setting (behaviour)	x	
Goal-setting (outcome)	x	
Feedback and monitoring		
Feedback on behaviour	x	
Social support		
Social support (unspecified)	X	x
Social support (emotional)	x	x
Shaping knowledge		
Instruction on how to perform behaviour	x	
Comparison of behaviour		
Demonstration of the behaviour	x	
Natural consequences		
Information about health consequences	x	
Repetition and Substitution		
Behavioural practice	x	
Graded tasks	x	
Comparison of outcomes		
Credible source	x	
Self-belief		
Verbal persuasion about capability	x	
Antecedents		
Restructuring the physical environment	x	
Adding objects to the environment	x	

2.8. Adverse events

We monitored all adverse events (including falls, surgical revisions, other non-fracture related appointments and surgeries, etc.) throughout the study. All participants were asked to report any injury or hospitalization (planned or unplanned) when it was safe to do so. We collected detailed information on the reported event and categorized the injury as adverse or serious adverse based on the National Institute of Aging (NIA) classification system [22]. A physician not involved in the study reviewed the detailed report on serious adverse events to adjudicate if it was related to the intervention. Events were classified as: Definitely not related, possibly related or definitely related to the intervention.

2.9. Statistical analyses

Our sample size was based on feasibility of recruiting n = 130 older adults with hip fracture within 18 months, and with 110 participants at final assessment (accounting for loss of participants) we would

have enough power to detect a difference in the primary outcome between groups using a Wilcoxon-Mann-Whitney test [14]. For recruitment, we calculated the percentage of older adults who were eligible for the study and the percentage of those who enrolled. We compared the age of eligible participants who enrolled with those who did not enrol using an independent t-test. We provide a percentage of participants who enrolled based on the recruitment mode employed. We defined reach using the definition by RE-AIM as the "*absolute number, proportion, and representativeness of individuals who are willing to participate in a given initiative*" [11]. We defined retention to the study as participants who completed at least one outcome at final assessment (12 months).

We provide a description of participants' baseline characteristics using mean (standard deviation), median (p10, p90) or percentage, depending on the variable. We provide percentages of participants who were within categories of frailty and walking speed at baseline [23]. We used odds ratios to describe differences between men and women for marital status and living arrangements. We calculated summary statistics for Clinic visits (by health professionals) using a chart review for intervention participants and provide the percentage of participants in each group who reported engaging in either a strength or balance activity at 12 months. For all analyses, we considered $p < 0.05$ as significant (two-tailed) and used SPSS Version 23 (IBM, Armonk, New York).

3. Results

3.1. Study recruitment

We screened 875 potential participants from May 2011 to April 2013 with the following results: 96 (11%) from the ward; 774 (88.4%) from hospital charts and/or discharge lists; and 5 (0.6%) from posters word or mouth. There were 562 participants (64%) not eligible for the study, despite our pragmatic inclusion criteria. The three most common reasons for non-eligibility were: Discharge to residential care (n = 141), < 65 years of age (n = 79) and participant diagnosis of dementia (n = 71). Of the participants who were eligible, the three most common reasons for declining participation were: We could not make contact (e.g. letter returned, no follow-up phone number, etc.) (n = 68), too tired/ill (n = 45), or did not speak English (n = 36). We did not reach our recruitment target of n = 130 older adults over 18 months [14].

3.2. Reach

From the list of all older adults who were eligible (and with whom we could make contact) we recruited 53/245 (22%). Based on the full list of eligible participants (regardless of whether we were able to make contact or not) we recruited (53/313; 17%) into the study. By recruitment mode, 5/53 (9%) participants were recruited and enrolled via the ward, 45 (85%) via a list, letter sent home and follow-up telephone call, and 3 (6%) from telephone enquiries. There was a significant difference in age (at screening) of older adults who enrolled in the study [79 (8) years], compared with older adults who did not enroll [83 (8) years], $p = 0.004$.

Retention: There were n = 51 participants who completed one or more measures at 12 months (96% retention); there were n = 49 participants who completed the primary outcome measure (SPPB) at 12 months: 92% retention (Figure 1).

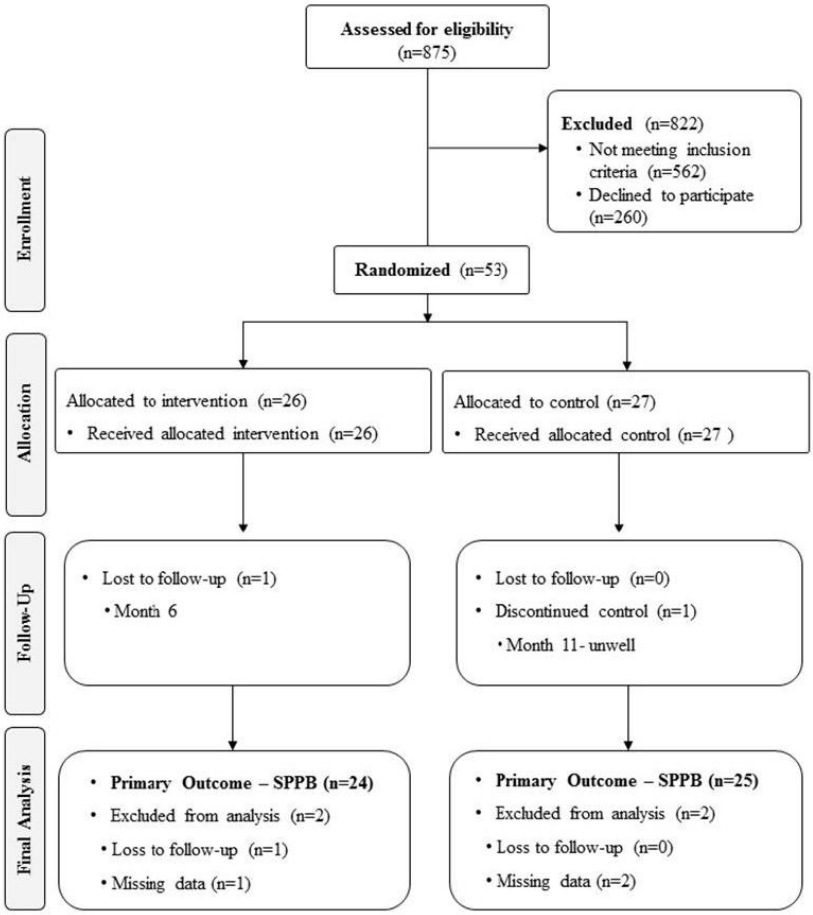

Figure 1. CONSORT 2010 flow diagram for the study.

3.3. Participants

Thirty-four women and 19 men enrolled in the study. The mean age (standard deviation) was 80 (8) years. Compared with women, men were more likely to be married (OR [95% CI]) (4 [1.17 to 13.66], $p = 0.027$) and living with someone (4.2 [1.16 to 15.36], $p = 0.029$). Participants were highly educated. All men had some university or education beyond secondary school. There were five women who did not graduate from high school, but the others completed high school and/or had more education beyond secondary school. Participants represented a range of frailty and mobility (based on walking speed). Please see Table 3.

3.4. Implementation

Adoption and capacity to deliver: One hospital-based outpatient clinical service (within the publicly funded provincial health care system) adopted this new iteration of the hip fracture follow-up clinic. We were able to identify (case-finding) and recruit participants to the Clinic, where they received the intervention within existing health care services.

Table 3. Baseline characteristics of participants who enrolled in the study.

	Overall (n = 53)	Men (n = 19)	Women (n = 34)
Women, N (%)	34 (64.2%)		
Age, mean (SD), y	80 (8)	80 (7)	80 (8)
Married, N (%)	28 (52.8%)	14 (73.7%)	14 (41.2%)
Living alone, N (%)	22 (41.5%)	4 (21.1%)	18 (52.9%)
Highest education level			
Some secondary school, N (%)	5 (9.4%)	0 (0%)	5 (14.7%)
Completed secondary school, N (%)	3 (5.7%)	0 (0%)	3 (8.8%)
Attended post-secondary school, N (%)	45 (84.9%)	19 (100%)	26 (76.5%)
Time since hip fracture, mean (SD), days	228 (77)	230 (78)	226 (77)
BMI (kg/m^2), mean (SD)	25.1 (3.6)	26.1 (3.4)	24.5 (3.6)
FCI, number of comorbidities, median (p10, p90)	3 (1, 6)	2 (1, 6)	3 (0, 7)
Pre-Fracture Mobility			
Able to walk 400 m pre-fracture, N (%)	48 (90.6%)	18 (95%)	30 (88%)
Mobility aid, N (%)	14 (26.4%)	3 (16%)	11 (32%)
Fried Frailty Score [48]			
Non-frail, N (%)	14 (26%)	6 (32%)	8 (23%)
Pre-frail, N (%)	27 (51%)	8 (42%)	19 (56%)
Frail, N (%)	12 (23%)	5 (26%)	7 (21%)
Walking speed [23]			
Cross street > 1.2 m/s	3 (6%)	1 (5%)	2 (6%)
Walks outside 0.8–1.19 m/s	23 (43%)	11 (58%)	12 (35%)
Limited outdoor walking 0.4–0.79 m/s	20 (38%)	4 (21%)	16 (47%)
Walks inside < 0.4 m/s	7 (13%)	3 (16%)	4 (12%)

BCTs: Table 2 presents the BCTs used during the study. We identified 12 techniques (of the available 93 BCTs) in this intervention. Most BCTs were in two clusters: Goals and planning, and social support. We do not know whether participants (from either group) were exposed to BCTs outside of our intervention.

Fidelity and dose of the intervention: All intervention participants received at least one assessment by the geriatrician, PT and OT, with additional appointments and/or referrals as needed. Table 1 provides more information related to intervention delivered and received. Outside of the intervention, participants from both groups attended physiotherapy sessions with a range of 0–59 sessions/12 months for intervention participants and 0–80 sessions/12 months for control participants, with only a few participants who had more than 12 PT visits/12 months in total. For exercise dose, there were more intervention participants who reported completing balance and strength activities at 12 months.

Maintenance: We report the number of participants who remained in the study at 12 months *(see retention above)*. In addition, we report how many participants completed balance and strength activities at 12 months (Table 1).

Adverse events**:** There were 36 participants (n = 17 intervention and n = 19 control group) who reported an adverse event at some point over 12 months. Of these, there were 21 participants who reported a serious adverse (n = 8 intervention and n = 13 control participants) event during their participation in the study including; five surgical revisions and five (non-hip) fractures. No adverse

events were adjudicated as being definitely related to the intervention. There was one serious adverse event (intervention group) that was possibly related to the intervention, but no follow-up action was required.

4. Discussion

Although a preponderance of rehabilitation intervention studies have been conducted, we know relatively little about factors that influence implementation and how implementation is linked to outcomes [12]. Supporting integration of evidence into practice requires a balance between rigor and relevance [5,24–26]—with an emphasis on disentangling design (and evaluation) of an intervention from its implementation (and how this may influence outcomes) [12]. We adopted implementation frameworks to describe the reach of the intervention for older adults with hip fracture, capacity to deliver the intervention, and implementation components of the innovation (reach, fidelity and dose) [11,12,27]. Frameworks guided the planning stage for implementation of the intervention, our implementation approach and implementation outcomes. We provide a detailed description of the target population, information to convey the internal validity of the trial, and describe specific operational details, such as BCTs, used to support future replication of the intervention. Together this descriptive implementation study will permit others to replicate our intervention and us to contextualize our findings within the main health outcomes.

Recruitment into research studies is particularly challenging, in general [28] and specifically for vulnerable populations such as some older adults [6]. Recruitment strategies adopted may also affect reach of the intervention [29]. Combined, these factors impact on who is included (and excluded) in the intervention, which does not always represent the population at risk. We note that many older adults with hip fracture were not eligible to participate despite us adopting a pragmatic research design. Of the three groups of older adults who most often sustain a hip fracture (i.e., older adults living in residential care/with cognitive impairment; community dwelling older adults with some impairments/frailty; and active community dwelling older adults) [30] our study does not represent the perspective of those living in residential care and/or with dementia. This is because our study (and others [1]) rely on older adults' cognitive skills (and/or family and friends' support) to complete research assessments, attend outpatient appointments, engage in exercises and other self-management strategies. Thus, from the beginning we included community-dwelling older adults as this seemed appropriate given that the intervention was delivered in an outpatient clinical setting. Further, participants who enrolled in this study were highly educated (90% finished high school) and were able to access rehabilitation (outside of the study); consequently, we are unable to generalize our results to older adults with low health literacy and/or living in areas with limited access to health professionals.

It is equally challenging to encourage older adults to continue to participate in the intervention and its evaluation over the course of a trial [31]. Despite this, we had excellent retention of study participants—over 90% at 12 months. This is especially significant given the high number of health related events that participants experienced over the course of the study. Although events were deemed as definitely unrelated to the intervention (with one event that was possibly related), they reflect challenges that older adults with hip fracture may be confronted with during the recovery period. In another study, we conducted semi-structured interviews with older adults in the early phase of hip fracture recovery (within the first four months of fracture) [32]. Other health related concerns (beyond the hip fracture) was a prominent theme; specifically, participants recounted challenges living with

multimorbidity and hip fracture [32]. However, strategies we employed to engage participants were frequent telephone contact, birthday and holiday cards, and a small stipend for participating. Incentives to encourage adherence and retention are important, however they may also be (inadvertently) interpreted as a "co-intervention". We previously reported (using semi-structured interviews at 6 and 12 months) [19] that participants from the control group felt assured knowing that someone from the study was available if they had questions. We also sent letters to participants' family physician (if permission was given) acknowledging their role in the study—this, too, may have affected participants (and their health care professionals') behaviour. Thus, by providing support to those in the control group we may have delivered a second intervention, and this may have influenced outcomes.

A prime motivation for this study was to address a gap in service and low rates of mobility recovery for older adults after hip fracture. An ortho-geriatric approach for hip fracture management is recommended [33], but is not always available in practice. When we started our study, the fracture liaison model was just beginning [34]; it has since been disseminated in many places around the world [35–37]. However, the distinct feature of the B4 Clinic was to target functional recovery after hip fracture (and reduction of falls risk factors), in addition to addressing bone health related issues [38]. In this study, we determined the ability to deliver the intervention, as planned. Based on our consistent tracking of eligible participants, we were able to identify the population and specific details of those most appropriate for this type of intervention. In doing so, we provide an example of embedding research within health service delivery.

In this trial, health professionals at the B4 Clinic assessed all intervention participants as per protocol. Fidelity and adherence are often used interchangeably; adherence is defined as "the extent to which the patient's [*person's*] behaviour matches agreed recommendations from the prescriber" (Horne et al, 2005, page 4) [39]. The World Health Organization notes that "adherence requires the patient's [*person's*] agreement to the recommendations" (WHO, 2003, page 4) [40]. However, adherence as a concept is challenging to define and operationalize [41]. In this study, we are aligned with the work of Sidani and colleagues [42], who defined adherence as *"attendance to treatment sessions and enactment of treatment recommendations"* [page 5]. Specifically, we tracked self-reported health professional visits and physical activity (specifically exercise) engagement (via a validated questionnaire during prospective monthly telephone calls and accelerometry—see Table 1). We recognise the limitations of using self-report data. Therefore, to mitigate these concerns we conducted a chart review to determine what aspects of the intervention each participant received at the Clinic. However, as our program was pragmatic we do not know the exact "dose" delivered by the health professionals or received by older adults. Other potential limitations associated with a chart review include missing or limited information recorded within each patient visit. Finally, although we tracked (monthly) participants' medical appointments, we do not know the details of these appointments outside of the Clinic, for intervention or control participants.

Despite the wealth of knowledge obtained in this clinical study, we recognize our limitations in recruiting older adults into the study. First, we require further investigation to determine if our recruitment rate would be higher if our protocols (for identifying and interacting with eligible participants) became part of the usual care pathway. Second, this study was able to highlight the importance of having administrative research support to connect case finding to care delivery: our project coordinator was able to bridge participants with health services. This important role takes time and resources and should be accounted for in any future clinical evaluation of the program. Third,

recruitment could be improved by making the intervention simpler for the participants. For example, establish clinics at nursing homes or assisted living sites for older adults with significant cognitive and/or physical impairment. Also, telerehabilitation delivery models should be explored for older adults with barriers to leaving the home.

Finally, our consistent interaction with participants may have created a co-intervention worth testing in the future. If monthly contact via telephone provides a degree of support for older adults, this may constitute an effective delivery mode for older adults with hip fracture: telerehabilitation.

5. Conclusion

We describe implementation factors (e.g., recruitment, reach) that might serve to explain results of our trial of comprehensive geriatric management for older adults' mobility after hip fracture. It seems imperative that these factors be considered in all studies so as to differentiate between elements of design and implementation of an intervention and how they alone or together might affect outcomes. We also note in this pragmatic trial embedded within a real-life clinical setting it was difficult to recruit participants. Participants who began largely completed the study—we speculate that our screening and clear explanation of the study, combined with a high level of attention to engaging participants on an ongoing basis provide the unusually high retention rate. This element of the intervention may be a useful guide for researchers who perform similar work. Overall, what we learned about implementation can be used to enhance the quality of research projects *and* clinical practice.

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Conflict of interest

The authors declare no conflict of interest in this paper.

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