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Pre-Clinical Mobility Limitation (PCML) Outcomes in Rehabilitation Interventions for Middle-Aged and Older Adults: A Scoping Review

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Article

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Résumé

Les personnes atteintes de limitations précliniques de la mobilité (PCML) présentent un risque élevé de déclin fonctionnel futur et de progression vers l'invalidité. Cette revue exploratoire visait à analyser l'ensemble des études sur les interventions auprès de personnes d'âge moyen et plus âgées atteintes de PCML. Nous présentons les interventions qui ont été testées ou planifiées, décrivons comment elles ont été menées et documentées, recensons les lacunes de connaissances dans la littérature actuelle et formulons des recommandations sur l'orientation de la recherche future. Parmi les 2 291 articles examinés, 14 ont été retenus comme étant conformes aux critères de la revue. Les conclusions révèlent les faits suivants : 1) le nombre des travaux publiés sur les interventions PCML, surtout auprès de populations d'âge moyen, est limité; 2) la complexité et la diversité des paramètres d'évaluation des limitations précliniques de la mobilité rendent difficile la comparaison des résultats des études à ce sujet. Malgré la diversité des paramètres, cette revue fournit des preuves préliminaires du fait que les interventions de réadaptation dans les cas de PCML contribuent à retarder ou à prévenir la progression vers l'invalidité.

Abstract

Individuals with pre-clinical mobility limitation (PCML) are at a high risk of future functional loss and progression to disability. The purpose of this scoping review was to provide a comprehensive understanding of PCML intervention studies in middle-aged and older adults. We present the interventions that have been tested or planned, describe how they have been conducted and reported, identify the knowledge gaps in current literature, and make recommendations about future research directions. An initial search of 2,291 articles resulted in 14 articles that met criteria for inclusion. Findings reveal that: (1) there is limited published work on PCML interventions, especially in middle-aged populations; and (2) the complexity and variety of PCML measures make it difficult to compare findings across PCML studies. Despite the diversity of measures, this review provides preliminary evidence that rehabilitation interventions on PCML help to delay or prevent disability progression.

Introduction

Disability means having difficulty or being unable to perform a range of activities (Rantakokko, Portegijs, Viljanen, Iwarsson, & Rantanen, 2017; Verbrugge & Jette, 1994). It is not an inevitable aspect of aging (Jehn & Zajacova, 2019); however, the rate of disability increases as people age (Government of Canada, 2011; Okoro, Hollis, Cyrus, & Griffin-Blake, 2018). Similar trends are found in mobility disability, the most common type of disability experienced by older adults (Government of Canada, 2011; Okoro et al., 2018). According to the 2011 Federal Disability Report (FDR), one in four Canadians 65–74 years of age experienced mobility disability. This increases to two in five Canadians 75–84 years of age and three in five for those 85 years of age and older (Government of Canada, 2011). Furthermore, middle-aged Canadians (40–64 years) have been experiencing flat or increasing disability trends across different demographics, such as level of education and province of residence (Jehn & Zajacova, 2019), which is particularly problematic, as these individuals represent our future older population.

Mobility refers to the ability to move oneself (independently or by using assistive devices or transportation) from one place to another (Webber, Porter, & Menec, 2010; World Health Organization, 2001) and to perform different activities in their environments (Siltanen et al., 2020). Mobility is considered a prerequisite for maintaining a good quality of life and is an important health outcome indicator in older adults (Abbott, 2009; Siltanen et al., 2020). Mobility

disability has been associated with increased mortality risk and health care utilization, as well as decreased functional independence and quality of life (Freiberger, Sieber, & Kob, 2020; Hardy, Kang, Studenski, & Degenholtz, 2011; Ni et al., 2017; Pruitt et al., 2008). Mobility loss with aging is commonly described as a downward trajectory with a steeper decline shown late in life (Ferrucci et al., 2016). However, age-related impairments in mobility-associated physiological systems can be compensated for by changing the manner or the frequency of performing a task requiring mobility (Ferrucci et al., 2016). Overt mobility disability only manifests when the severity of the mobility deficit becomes too severe to be compensated for (Ferrucci et al., 2016). The intermediary phase, occurring with progressive loss of function and preceding the onset of disability, is referred to as "pre-clinical disability" (Fried, Herdman, Kuhn, Rubin, & Turano, 1991), "pre-clinical mobility disability" (Fried et al., 1996), or "pre-clinical mobility limitation"(Mänty et al., 2007). According to a recent study (Richardson, Beauchamp, Bean, et al., 2023), a consensus among a group of international experts in pre-clinical disability highlights that the concept of pre-clinical disability should encompass task modification, particularly routine mobility tasks, so that these tasks can be performed without visible disability. As a result, the study introduced Pre-clinical Mobility Limitation (PCML) as the preferred term, which was utilized for this review.

PCML was first conceptualized by Fried et al. (1991). They defined it as a functional stage at which people can compensate for functional decline by modifying their task performance and thereby maintaining their function without reporting outright difficulty (Fried et al., 1991). Evidence demonstrates that people reporting PCML are at an elevated risk of experiencing future overt disability in physical performance (Fried et al., 1996; 2001; Mänty et al., 2007). Additionally, it is suggested that PCML is associated with the onset of multiple adverse health outcomes such as falls, depressed mood, and obesity in older adults (Clough-Gorr et al., 2008; Hirvensalo et al., 2007; Mänty et al., 2010; Naugle, Higgins, & Manini, 2012; Wolinsky et al., 2007). PCML is proposed as "an early warning system" for altered risk factors (Fried, Bandeen-Roche, Chaves, & Johnson, 2000; Wolinsky et al., 2007). Individuals in this transition stage may represent an optimal group to receive interventions on prevention rather than recovery when one or multiple domains of disability is established (Clough-Gorr et al., 2008; Gregory et al., 2011; Higgins et al., 2012). In the primary prevention of disability among older adults, intervening in the PCML period may be a uniquely effective strategy to reduce the burden of disability in this population (Weiss, Hoenig, & Fried, 2007). For older adults experiencing overt disabilities in performing some tasks, identifying other tasks for which pre-clinical modification has been reported has also been found to be an effective prevention strategy (Young, Boyd, Guralnik, & Fried, 2010).

Although empirical findings provide sufficient evidence to move toward interventional studies targeting PCML, studies in this field have provided inconclusive results. For example, in a 12-week single-blinded randomized controlled trial (RCT) involving older adults with pre-clinical gait dysfunction, it was shown that a motor learning program, when compared with a standard treadmill walking program, resulted in improvements in mobility performance parameters, such as gait speed and motor skill (Brach et al., 2013). Furthermore, in a 12-month quasi-experimental trial, it was discovered that older adults with PCML participating in a physical therapy program augmented with mobile tele-health technology exhibited significant differences in gait speed compared to controls (Bean et al., 2019). However, other RCT studies reported little changes in impairments or functional limitations for older adults with PCML engaged in a 24-week Tai Chi or seated flexibility exercise program (Day et al., 2012). Many factors may contribute to these conflicting findings, such as tools used to identify PCML stage, participants' eligibility criteria, and interventions selected. A preliminary search also showed that the outcomes measuring changes in PCML vary among studies (Day et al., 2012; Neil-Sztramko et al., 2020; Richardson et al., 2008). Some used self-reported measures, such as the pre-clinical disability screening tool by Fried et al. (2001) or the Pre-clinical Mobility Disability Scale by Mänty et al. (2007), whereas others argued that performance-based measures can identify limitations in physical function better than self-report measures (Brach et al., 2013). In addition, the heterogeneity of the recruited samples' characteristics (e.g., age, gender, cognitive level) and the variation in the intervention used (e.g., type, frequency, length, intensity, and delivery professions) may also contribute to the variation in results.

Therefore, it would be productive to understand the types of interventions used to address issues of PCML, the measures employed to assess PCML changes, and the characteristics of the participants with PCML recruited for interventional studies. To our knowledge, there are no reviews that have synthesized PCML interventions. This scoping review aims to provide a comprehensive understanding of PCML intervention studies in middle-aged and older adults that have been tested or planned, describe how they have been conducted and reported, identify the knowledge gaps in current literature, and make recommendations about future research directions regarding interventions for PCML. Specifically, the review questions are:

- What types of rehabilitation interventions are used to address PCML in middle-aged and older adults?
- What measures are used to assess PCML changes in intervention studies? What measures are used to assess other outcomes in these intervention studies?
- What are the characteristics of the baseline samples included in the PCML intervention studies (e.g., participants' baseline characteristics, eligibility criteria, PCML stage assessment)?

Methods

This review was conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (PRISMA-ScR) checklist (Tricco et al., 2018) and the JBI approach developed by JBI and the JBI Collaboration (JBIC) group (Peters et al., 2020). The JBI approach was underpinned by the methodological frameworks initially proposed by Arksey and O'Malley (2005) and further enhanced by Levac, Colquhoun, and O'Brien (2010). This scoping review was registered with Open Science Framework (https://osf.io/b6zr4). A detailed review protocol was posted on medRxiv (https://medrxiv.org/cgi/content/short/2022.10.22.22280644v1). The PRISMA-ScR Checklist was also included (Appendix III).

Eligibility Criteria

For inclusion in this review, articles had to meet the following criteria: reporting rehabilitation interventional studies on middle-aged individuals (45–64 years) or older adults (≥ 65 years of age) with PCML outcomes, or reporting functional change outcomes consistent with the PCML stage. Measurements used to determine participants' PCML stage and assess PCML changes could include either self-reported measures or physical performance measures, as long as the term PCML or its synonym (e.g., pre-clinical disability, subclinical disability, perceived disability) was indicated explicitly in

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the studies. Additionally, any non-surgical or non-pharmacological intervention could be considered a rehabilitation intervention, following the definition provided by McGlinchey et al. (2018). Studies using a single-component rehabilitation intervention or as a part of a multifaceted intervention were included, regardless of frequency, intensity, length, and who delivered them. Because of limited evidence in this field, various study designs were considered, including RCTs, non-randomized controlled trials (NRS), controlled clinical trials, pre-post studies, interrupted time series studies, uncontrolled longitudinal studies, case studies, registered trials, and protocols. Abstract-only publications were not considered for inclusion. Studies published in languages other than English were excluded because of limited resources for translation.

Data Sources and Search Strategies

Seven electronic databases (MEDLINE®, Embase, Allied and Complementary Medicine Database [AMED], PsycInfo, Cumulative Index to Nursing and Allied Health Literature [CINAHL], Web of Science, and Cochrane CENTRAL) were used to locate relevant intervention studies (English evidence from inception to March 19, 2022). The search strategy was generated using the Population, Concept, Context (PCC) framework and refined after consulting with a McMaster research librarian. The text words included in the titles and abstracts of relevant articles ([preclinical* OR pre-clinical or subclinical* OR sub-clinical or incipient* OR perceived OR early] adj3 [mobility OR function* OR physical] adj3 [disab* OR declin* OR limit* OR deficit* OR dysfunction* OR impair* OR difficult* OR deteriorat* or modif*]) and the index terms used to describe the articles ("middle aged" or "aged" or "aged, 80 and over") were used to develop a complete search strategy for Ovid MEDLINE (see Appendix I). The search strategy was tailored to the specific requirements of each included database, including all identified keywords and index terms. Google Scholar was utilized to identify any other primary sources within grey literature. In addition, a hand search of the reference list of retrieved articles and review articles was conducted to identify any further studies not yet captured. A follow-up search was implemented over 3 months, ending on July 2, 2022, to identify additional articles after the initial search on March 19, 2022.

Study Selection

Titles and abstracts of all identified citations were imported into Covidence (Veritas Health Innovation, Melbourne, Australia), and duplicated citations were removed. A calibration exercise was undertaken by two reviewers (A.L. and A.M.) independently screening 20 citations to evaluate reviewer agreement and identify any revisions required in the screening process. Following the calibration period, the two reviewers (A.L. and A.M.) independently conducted the title and abstract screening and full-text screening. Attempts were made to contact the source author for articles with missing or unclear data. Any disagreements on study selection were resolved by discussions or consensus involving a third reviewer (J.R.). Reviewers were not blinded to author or journal information.

Data Extraction

A data extraction form was developed to chart characteristics of the selected studies such as study design, sample size, participants' characteristics (age, gender, setting) by group (intervention vs. comparator), and specific details about the interventions (e.g., content length, frequency, single or multifaceted, outcomes reported) (see Appendix II). The form was reviewed, pilot-tested, and modified by the reviewers (A. L., A.M., J.R.) before the full-text review process. Two reviewers (A. L. and A.M.) conducted the data extraction independently and discussed any conflicts that arose.

Data Synthesis

The extracted data were presented in tabular form that aligns with the research questions of this scoping review. The type, content, length, intensity, and frequency of interventions were presented, as well as whether they were delivered as a single method or part of a multifaceted approach. Participants' characteristics were presented by listing age, gender (% of female), per cent of participants identified as being at the stage of PCML, and the measurements used. Self-reported or physical performance measured PCML outcomes and other outcomes reported in the studies were also presented. A narrative summary accompanied the tabulated results and described how the results relate to the review questions.

Results

Selection of PCML Interventional Studies

Using the key search descriptors, 2,291 potentially relevant studies were yielded after 2,061 duplicates were removed (Figure 1). After abstract screening and full-text reviewing, a total of 15 studies met the eligibility criteria and 14 of them were selected for this review (see Appendix IV), with one being excluded because of missing critical data. A large number of studies (n = 2,245) were excluded upon screening at the title and abstract stage because the key terms used in the search strategy also corresponded to other study designs (e.g. cross-sectional study) or the pre-clinical phase of other diseases (e.g., Alzheimer's disease, hypothyroidism). Thirty-two studies not meeting the eligibility criteria were excluded during the data extraction stage. The reasons for exclusion were: "inappropriate patient population (n = 17)", "inappropriate study design (n = 5)", "abstract only (n = 4)", "duplicate (n = 4)", "non-English publication (n = 1)", and "missing data (n = 1)" (Figure 1).

Characteristics of Included Studies

All included studies were published from 2008 onwards, over the 15 years since PCML was conceptualized by Fried et al. (1991). Two protocols (Ni et al., 2017; Rantanen et al., 2019) and their respective published articles (Bean et al., 2019; Siltanen et al., 2020) were grouped, resulting in a total of 12 studies being reported. Of those, 11 were RCTs, and one was an NRS (quasi-experimental). Five were conducted in the United States (42%), three in Canada (25%), two in Finland (17%), and two in Australia (17%). Most studies employed exercise as an intervention type, making up 58.3% (7/12) of trials. Other than one study with no clear statement (Brach et al., 2013), studies indicated that they recruited community-based samples.

Results of Individual Sources of Evidence

The findings were organized based on the scoping review questions: (1) sample characteristics, (2) intervention type, (3) PCML measures, (4) measures to assess other outcomes, and (5) changes in PCML outcomes.

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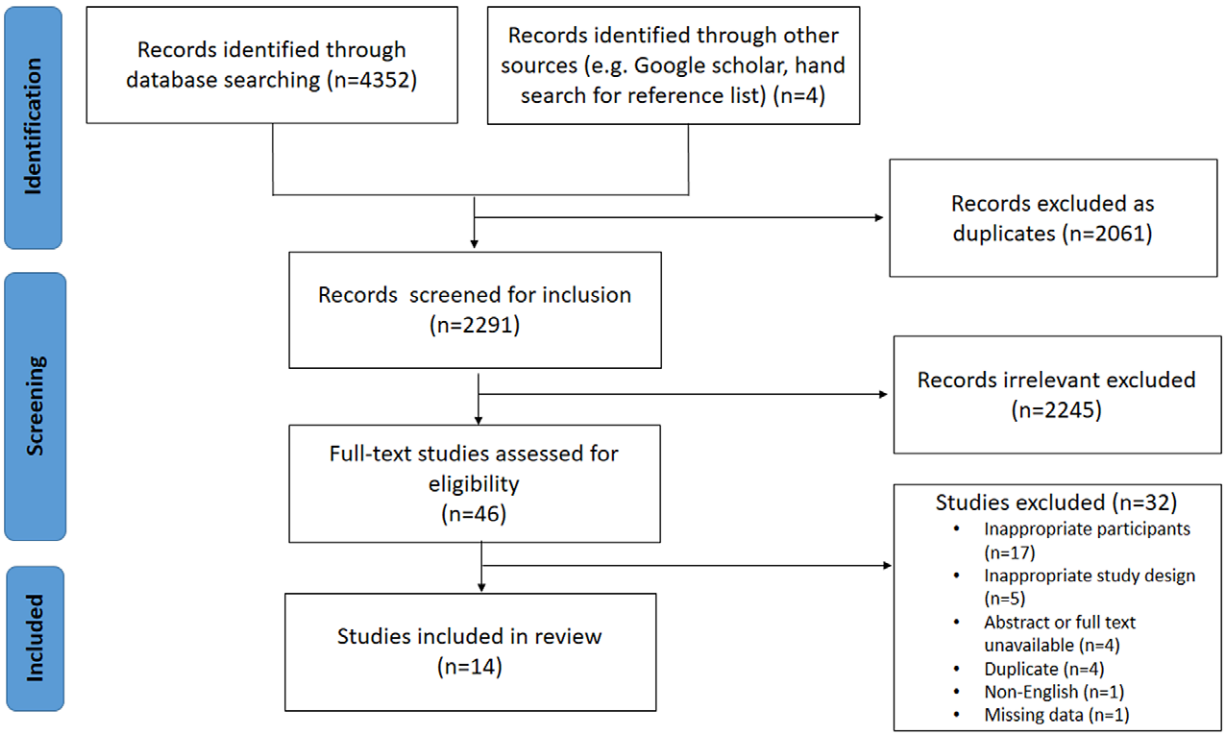

Figure 1. PRISMA flow diagram of study selection.

Sample characteristics

Of the 12 studies, most (n = 8) indicated a specific PCML stage assessment as one of the inclusion criteria, including subclinical gait dysfunction and impaired motor skill in walking (n = 1) (Brach et al., 2013); Fried Self Report Task Modification and Disability Scale (Fried scale) (n = 4) (Bean et al., 2019; Bennett & Hackney, 2018; Day et al., 2012, 2015); Manty Pre-clinical Mobility Disability Scale (Manty scale) (n = 2) (Edgren et al., 2019; Richardson et al., 2020); and Task Modification Scale (MOD) (n = 1) (Manini et al., 2007). There was only one study that considered middle-aged (≥ 40 years) participants (Neil-Sztramko et al., 2020); all others had an inclusion criteria of being at least 55 years of age, which is often the youngest age for being considered a "Senior Citizen" (https://www.seniorliving.org/life/senior-citizen/). Other than age and PCML stage measures, inclusion criteria related to cognitive level (n = 6) and medical condition (n = 8) were used. The Mini-Mental State Examination (MMSE) was the most frequently used measure in these studies (4/6, 66.7%), but the eligibility cut-off scores varied across studies, with the lowest score being 18 (Bean et al., 2019) and the highest being 25 (Siltanen et al., 2020). Among the 12 studies, eight explicitly specified that participants needed to be medically stable (Brach et al., 2013), have no major illness (Richardson et al., 2020), receive clearance from physicians (Day et al., 2012, 2015; Moore-Harrison et al., 2008), or achieve a designated cut-off score on functional tests such as the Short Physical Performance Battery (SPPB) with a baseline score of 4–12 and < 20% in the range of 11–12 for the intervention group (Bean et al., 2019); or the Life Space Assessment (LSA) with a baseline score of 52.3–90 (Siltanen et al., 2020), or demonstrate the ability to walk 500 m unaided in a walking test (Edgren et al., 2019).

Although four studies did not require the PCML stage measure as an eligibility criterion (Moore-Harrison et al., 2008; Neil-Sztramko et al., 2020; Richardson et al., 2008; Siltanen et al., 2020), all studies included a PCML measurement. All or a portion of the participants were identified as individuals at the PCML stage, except for in two protocols that had not completed participant recruitment at the time of submission (Edgren et al., 2019; Richardson et al., 2020). Participants in the 10 completed studies were all older adults ≥ 55 years of age, including both genders. The sample size in the studies varied depending on the intervention type. Studies using exercise as an intervention either had small recruitment (n = 20–40) or high drop-out rates and low attendance, which resulted in a relatively small sample size. However, studies using other types of interventions had larger sample sizes. For example, 237 participants were included in an educational intervention study (Richardson et al., 2008) and 510 participants were recruited using a knowledge translation intervention (Neil-Sztramko et al., 2020) (see Table 1).

Intervention type

Only one study used a multifaceted intervention (exercise combined with a mobility self-management [SM] program, Richardson et al., 2020), while all others used a single intervention. Exercise was the most frequently used intervention type in the studies (7/12, 58.3%) (Bennett & Hackney, 2018; Brach et al., 2013; Day et al., 2012, 2015; Manini et al., 2007; Moore-Harrison et al., 2008; Richardson et al., 2020). Of these, four studies used other exercise types as controls, one compared exercise to usual care (Brach et al., 2013), one compared it to a nutrition intervention (Moore-Harrison et al., 2008), and one compared to participants' initial status, which was 8–10 weeks before the intervention. During the control period, all participants continued their usual activity for 8–10 weeks and were then randomly assigned to intervention groups (Manini et al., 2007). Other types included an educational intervention (Richardson et al., 2008), tele-physical therapy (Bean et al., 2019), knowledge translation (Neil-Sztramko et al., 2020), and counselling (Edgren et al., 2019; Siltanen et al., 2020). The duration of exercise interventions in the studies was shorter (8–48 weeks)

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Table 1. Main findings of included studies

Author, Publication Year, Country	Sample size[a], characteristics- Setting, Age (Mean, SD), Sex (F%),	Study Design	Eligibility Criteria	% with PCML & PCML measures	Intervention vs. Control	Measurement	Study Outcomes
Brach et al., 2013 (USA)	• Sample size: Total (38); IG (18), CG (20) • Setting: unknown • Age: IG (75.7, 5.5); CG (78.5, 6.2) • Sex: IG (55.6%); CG (68.4%)	RCT (single blinded)	Including if • MMSE ≥ 24 • Medically stable • Subclinical gait dysfunction[b]	100%; gait speed and motor skill in walking	• Motor learning • Exercise intervention led by PT: task-oriented motor learning exercise program+ warm up+ progressive strength training. 60 min, twice/wk, 12 wks • Standard exercise as controls	• PCML outcomes measured by gait speed and motor skill in walking • Others: gait efficiency measured by energy cost of walking; walking endurance by 6 MWT; lower extremity strength by repeated chair rise component of SPPB; function and disability by LLFDI	• PCML outcomes improved in IG: Yes vs. CG • % of PCML participants decreased in IG: not measured
Moore-Harrison et al., 2008 (USA)	• Sample size: Total (24); IG (12), CG (12) • Community-dwelling • Age: unknown • Sex: IG (83.3%); CG (83.3%)	RCT	• Received medical clearance for inclusion • No information on PCML stage eligibility	85% (*n*=22); CS-PFP10	• Supervised • Walking intervention: warm up + walking + cool down. Moderate intensity (60-75% HRmax/RPE 12-14), 3 times/wk, 16 wks • Nutrition intervention as controls	• CS-PFP10 <57 (55-58) indicates PCML • Others: self-reported physical function assessed by SF36PF; SPPB; PPT; PAC by a modified Balke treadmill protocol; lower limb extension strength by a leg press machine	• PCML outcomes improved in IG: Yes vs. CG • % of PCML participants decreased in IG: Yes
Richardson et al., 2008 (Canada)	• Sample size: Total (237); IG (122), CG (115) • Community-dwelling • Age: IG (73.61, 5.94); CG (73.89, 6.29) • Sex: IG (53.6%); CG (55.1%)	RCT	No information	Because no cut-off score on Fried scale, hard to determine whether or not the % of them are in PCML stage	• Educational • intervention: PT/OT's feedback on assessment results + patient record + physician's feedback on the information. Attended the functional status lab on baseline, 9 mos, 18 mos • Controls: no assessment results nor survey received	• PCML outcomes measured using Fried scale (all 27 items) • Others: Health status by HUI3 & SF-36; lower extremity & grip strength; functional capacity by walk test, chair stands, balance tests, self-care, instrumental skills and communication by SAILS, functional abilities by NPPS; services utilization, no. of falls, exercise attendance, log notes	• PCML outcomes improved in IG: Yes vs. CG • % of PCML participants decreased in IG: not measured
Bean et al., 2019 (USA); Ni et al., 2017 (USA)	• Sample size: Total (168); IG (68), CG (100) • Community-dwelling • Age: IG (77.4, 6.0); CG (77.4, 7.3) • Sex: IG (52.94%); CG (55%)	NRS (quasi-experimental)	• Excluding MMSE<20 for IG and <18 for CG • IG: baseline SPPB score of 4-12 with < 20% in 11-12; CG: excluding baseline SPPB <4 & score 11 or 12 once reached 12% & 10% • Fried scale for PCML eligibility	100%; Fried scale	• REACH intervention: a tele-PT program combined outpatient and home PT (average 1-10 in person visits over 9 mos) augmented with a commercially available app and computer tablet • Matched controls from RISE longitudinal study	• Not indicated as PCML outcome but habitual gait speed on walking 4 m (one test of SPPB) reported in the study • Others: LLFDI; SPPB; the rates of ED visits	• PCML outcomes improved in IG: Yes vs. CG • % of PCML participants decreased in IG: not measured

(Continued)

Table 1. *Continued*

Author, Publication Year, Country	Sample size[a], characteristics- Setting, Age (Mean, SD), Sex (F%),	Study Design	Eligibility Criteria	% with PCML & PCML measures	Intervention vs. Control	Measurement	Study Outcomes
Ni et al., 2017	• Protocol of Bean et al., 2019 study						
Day et al., 2012 (Australia)	• Sample size: Total (361); IG (171), CG (190) • Community-dwelling • Age: 70-74 yrs IG (33.3%); CG (32.9%) 75-79 yrs IG (31.7%); CG (31.2%) 80-84yrs IG (24.1%); CG (23.5%) 85-89yrs IG (10.1%); CG (11.1%) >90yrs IG (0.8%); CG (1.3%) • Sex: IG (66.2%); CG (69.7%)	RCT	• Excluding if SPMSQ > 4 • Doctor's approval required for inclusion • Fried scale for PCML eligibility: no difficulty with either mobility task (walking and climbing stairs), but having changed the way in which at least 1 task is performed.	100%; Fried scale	• Modified 46 • forms Sun style tai chi intervention. 48 wks, twice weekly for 60 min per session • Flexibility and stretching program as controls	• No PCML outcomes reported • Others: physical function and disability measured by LLFDI; musculoskeletal impairment by spring gauge test and WOMAC; neurologic impairment by postural sway and single leg stand; cardiovascular impairment by BP and HR B/A 6 MWT; functional limitations by TUG, step test, chair stands, 6 MWT, 2 elements of BBS, and WOMAC for PA difficulty; depression by BDI	Not measured
Day et al., 2015 (Australia)	• Sample size: Total (409); IG (204), CG (205) • Community-dwelling • Age: IG (77.6, 5.1); CG (77.8, 5.0) • Sex: IG (69.6%); CG (69.8%)	RCT	Same as Day et al., 2012	100%; Fried scale	Same as Day et al., 2012	• No PCML outcomes reported • Others: reported falls for up to 48 wks, and other outcomes same as Day et al., 2012	Not measured
Neil-Sztramko et al., 2020 (Canada)	• Sample size: baseline & intention-to-treat analysis IG (256), CG (254) Completed data at all time points: IG (178), CG (182) • Community-dwelling • Age: IG (64.7, 8.5); CG (64.6, 8.2) • Sex: IG (85.2%); CG (83.5%)	RCT	No information	IG: 7.8% & CG: 10.7%; Manty scale	• Knowledge translation intervention: access Portal "Mobility and Physical Function" browse page + weekly e-mail on healthy aging related evidence + invited to follow a study-specific hashtag on Twitter & Facebook. 12 wks • Controls access portal in a "self-serve" fashion	• Level of mobility limitation measured using Manty Scale • Others: change in self-reported PA measured by RAPA; self-rated health; electronic health (eHealth) literacy; knowledge of recommendations; satisfaction and use of each of the KT strategies; a qualitative process study	• PCML outcomes improved in IG: not measured • % of PCML participants decreased in IG: Both IG and CG decreased but no significance between groups
Manini et al., 2007 (USA)	• Sample size: Total (32); RT (11), FRT (11), FT (10) • Community-dwelling • Age:	RCT	Including if • A peak knee extension strength to body weight ratio < 3.00 Nm/kg	MOD score & timed performance	• Type 1- RT: 3 lower + 3 upper body exercise for 2 work sets with 10 repetitions maximum per set + warm up;	• PCML measured using no. of task modifications and timed performance on 8 tasks of daily life	• PCML outcomes improved in IG: yes vs. pre-control period • % of PCML participants decreased in IG: not measured

(Continued)

Table 1. *Continued*

Author, Publication Year, Country	Sample size[a], characteristics- Setting, Age (Mean, SD), Sex (F%),	Study Design	Eligibility Criteria	% with PCML & PCML measures	Intervention vs. Control	Measurement	Study Outcomes
	IG/post-control (75.8, 8.4); CG/pre-control (75.9, 8.2) • Sex: IG (90.6%); CG (90%)		• Self-reported their ability to rise from a chair or climb a flight of stairs having "some" or "a lot" of difficulty in either task but modified way in either task		• Type 2- FT: 5 daily activity exercises. Type 3- combined RT & FT: 1 day for each. twice/wk for 10 wks, 20 sessions. 30-45 min per session • Participants' pre-control status[c]	• Others: knee & elbow strength body composition; self-reported physical function assessed by SF-12v2, single-leg balance time, walking speed >7.62m; upper body function by time to vacuum a carpet	
Bennett & Hackney, 2018 (USA)	• Sample size: Total (23); IG (12), CG (11) • Community-dwelling • Age: 73.4, 8.4 • Sex: IG (83.3%); CG (90.9%)	RCT	Excluding if • use of ambulatory aids; • neurological conditions; • use of portable oxygen, internal cardiac defibrillator, or myocardial infarction within past 6 mos. Including if • self-reported • difficulty walking 0.4 km or a flight of stairs	Fried scale. no reports on diff walking 0.4 km. SPPB was tested which includes gait speed test (timed 4m walk)	• Exercise intervention: 40 min low impact line dancing + 10 min warm-up + 10 min cool-down. Twice a week for 8 wks • Usual care as • controls	• PCML assessed by Fried scale • Others: Balance assessed by BBS; muscle strength of knee extensors and knee flexors of dominant side using the Nicholas Manual hand-held dynamometer; lower extremity function by SPPB; endurance by 400m walk	• PCML outcomes improved in IG: yes vs. CG measured as gait speed and difficulty climbing stairs but not in walking 0.4 km. • % of PCML participants decreased in IG: not measured
Siltanen et al., 2020 (Finland); Rantanen et al., 2019 (Finland)	• Sample size: Total (204) self-reported PA: Total (139); IG (67), CG (72) For average acceleration: Total (203) • Community-dwelling • Age: 75yrs IG (74%); CG (75%) 80yrs IG (26%); CG (25%) • Sex: IG (60%); CG (61%)	RCT	Including if • MMSE≥ 25 • Baseline LSA 52.3-90 • No information on PCML eligibility but states including those "have room for improvement in activity levels and whose cognitive function enables compliance with the intervention"	IG: 81% & CG: 84%; Manty scale on 2km walking	• Counseling + semistructured protocol concerning participants' current activities, goals, and action plans. 90 min face-to-face counselling session at the beginning and 4 shorter phone counseling sessions at 1, 3, 6, and 9 mos. Newsletter sent every 3 mos. 12 mos. • Controls were mailed brochures & booklets at 1, 3, 6, 9 mos	• Perceived walking difficulties assessed by Manty scale for 2 km walking • Others: physical performance assessed by SPPB; life-space mobility and autonomy in outdoor mobility assessed by UAB LSA; self-reported PA by 2nd part of YPAS; monitored PA by wearing a triaxial accelerometer[d]	• PCML outcomes improved in IG: not measured • % of PCML participant decreased in IG: decrease but no significant change
Rantanen et al., 2019	• Protocol of Siltanen et al., 2020 study						
Edgren et al., 2019 (Finland)	• Sample size: target 249 in total • Community-dwelling • Age: NA • Both sexes will be recruited	RCT protocol	• MMSE ≤ 21 for exclusion • Severe functional limitations (unable to walk 500 m unaided) for exclusion • Manty scale for PCML eligibility: at least minor self-reported mobility difficulty (i.e. task modification) in one or more tasks (walking 2.0 km,	NA	• Health and physical activity counselling intervention: 5 individually tailored 1.5 h face-to-face sessions at wk 1, 1 mo, 3 mo, 6 mo, 12 mos. Health counselling follows the motivational interviewing concept. 11 supportive phone calls	• Mobility difficulty will be assessed using Manty scale • Fall outcomes; • LSA; PA by Hookie AM 20; physical performance; HQoL by WHOQOL; mood by GDS; cognitive by MMSE; balance confidence by ABC; self-	NA

(Continued)

Table 1. *Continued*

Author, Publication Year, Country	Sample size[a], characteristics- Setting, Age (Mean, SD), Sex (F%),	Study Design	Eligibility Criteria	% with PCML & PCML measures	Intervention vs. Control	Measurement	Study Outcomes
			walking 0.5 km, climbing up one flight of stairs)		• PT-structured relaxation exercises as controls	reported physical ability; perceived exertion by RPE; intervention adherence; adverse events; body composition; fracture risk by FRAX; cardiovascular condition; services utilization; living arrangement; alcohol consumption; need of mobility aids	
Richardson et al., 2020 (Canada)	• Sample size: target 450 with 225 each for IG & CG • Community-dwelling • Age: NA • All gender will be recruited	RCT registration	• MoCA score <11 or major illness for exclusion • Manty scale (walking in 2km) for PCML eligibility	NA	• Stepping-Up Intervention: task-oriented motor learning exercise + a mobility self-management (SM) program. A 2 h virtual session/wk. 12 wks • Controls: telephone-based coaching walking program, TELE group and Chair-based Yoga group	• PCML will be assessed using Manty scale (walking on 2km) • Others: walking speed (4m gait speed); exercise capacity; lower body strength; dual task cost; self-reported change in mobility; balance self-efficacy; mobility patterns; knowledge, skill and confidence for SM; balance; HQoL; self-efficacy for PA; health care utilization data	NA

Note.
[a]Refer to the sample size analyzed unless otherwise noted.
[b]Defined as near-normal gait speed (≥1.0 m/sec walked at their usual, self-selected speed on a 4-m instrumented walkway) and impaired motor skill in walking (figure of 8 walk test (≥8 sec)
[c]Participants were initially tested (pre-control) and asked to continue their normal daily activities for an 8–10-week control period, tested again (post-control) and randomly assigned to intervention groups.
[d]Only those who participated in the pre-trial monitoring (n = 139, 68% of the total sample) were invited to participate in the post-trial monitoring.
RCT = randomized controlled trial; NRS = non-randomized controlled trials; PCML = pre-clinical mobility limitation; IG = intervention group; CG = control group; MMSE = Mini-Mental State Examination; SPPB = Short Physical Performance Battery; MoCA = Montreal Cognitive Assessment; RT = resistance training; FRT = functional + resistance training; FT = functional training; LLFDI = Late-Life Function and Disability Instrument; CS-PFP10 = Continuous Scale Physical Functional Performance 10 item test; SF36PF = Medical Outcome Survey- SF36 Physical Function; PPT = Physical Performance Test; PAC = peak aerobic capacity; SF-36 = Short Form-36; SAILS = Structured Assessment of Independent Living Skills; NPPS = Nagi Physical Performance Scale; ED = emergency department; WOMAC = Western Ontario and McMaster Universities Arthritis Index Osteoarthritis Index; BP = blood pressure; HR = heart rate; 6 MWT = 6-Minute Walk Test; BBS = Berg Balance Scale; BDI = Beck Depression Inventory; PA = physical activity; TUG = Timed Up and Go Test; RAPA = Rapid Assessment of Physical Activity; KT = knowledge translation; LSA = Life-Space Mobility Assessment; HQoL = health-related quality of life; WHOQOL = WHO Quality of Life; ABC = Activities-Specific Balance Confidence Scale; RPE = Borg Rating of Perceived Exertion scale; FRAX = WHO Fracture Risk Assessment Tool; SM = self-management; SPMSQ = Short Portable Mental Status Questionnaire; HUI3 = Health Utilities Index- Mark III; B/A = before and after; UAB LSA = University of Alabama at Birmingham Study of Aging Life-Space Assessment; YPAS = Yale Physical Activity Survey; GDS = Geriatric Depression Scale

with an average of 22 weeks compared with that of other intervention types, which mainly lasted 12 months or longer (Table 1).

PCML measures

As outlined in Table 1, not all studies assessed PCML outcomes, and there were various measures of PCML in the studies where this was assessed. The Manty scale was the most frequently used measure in the studies, including two RCTs (Neil-Sztramko et al., 2020; Siltanen et al., 2020) and two RCT protocols (Edgren et al., 2019; Richardson et al., 2020). However, the questions selected from the Manty scale also varied among these four studies: some asked about the difficulties in 2 km walking (Richardson et al., 2020; Siltanen et al., 2020), and others added questions about difficulties in 0.5 km walking and climbing up one flight of stairs (Edgren et al., 2019; Neil-Sztramko et al., 2020). Additionally, in one RCT (Siltanen et al., 2020), there was no explicit indication of whether the question regarding task modification had been further asked for those responding "able to manage without difficulty" to 2 km walking. The study also only categorized two groups, rather than three or four groups, as suggested in previous studies (Mänty et al., 2007, 2010). The Fried scale (Fried et al., 1996) was used to assess PCML outcomes in two studies (Bennett & Hackney, 2018; Richardson et al., 2008). However, one of them (Bennett & Hackney, 2018) only used seven items of activities instead of the 27 items recommended in the Fried scale (Fried et al., 1996). Continuous Scale Physical Functional Performance 10 Item Test (CS-PFP10), MOD and timed performance on eight tasks of daily life, and gait speed and impaired motor skill in walking were used in one study each (Brach et al., 2013; Manini et al., 2007; Moore-Harrison et al., 2008). Gait speed over 4 m was also assessed in three studies as a component of the SPPB (Bean et al., 2019; Bennett & Hackney, 2018) or as an independent test (Richardson et al., 2020). However, these studies did not specify it as a PCML outcome measure.

Measures to assess other outcomes

There were outcomes other than those for the PCML measured in these interventional studies. These measures were grouped into eight major categories according to the functional dimension/domain they evaluated.

1. Physical function and disability outcomes: self-report Late-Life Function and Disability Instrument (LLFDI) (Bean et al., 2019; Brach et al., 2013; Day et al., 2012), Nagi Physical Performance Scale (NPPS) (Richardson et al., 2008), and complete SPPB (Bean et al., 2019; Bennett & Hackney, 2018; Edgren et al., 2019; Moore-Harrison et al., 2008; Siltanen et al., 2020) or part of SPPB such as chair stands (Day et al., 2012; Richardson et al., 2008).
2. Balance outcomes: number of falls (Day et al., 2015; Edgren et al., 2019; Richardson et al., 2008), balance tests such as single-leg balance time or Berg Balance Scale (BBS) or Timed Up & Go (TUG) (Bennett & Hackney, 2018; Day et al., 2012; Edgren et al., 2019; Neil-Sztramko et al., 2020; Richardson et al., 2008), balance confidence assessed by Activities-specific Balance Confidence Scale (ABC Scale) (Edgren et al., 2019), and balance self-efficacy (SE) (Richardson et al., 2020).
3. Lower extremity strength (Brach et al., 2013; Manini et al., 2007; Moore-Harrison et al., 2008; Richardson et al., 2008, 2020).
4. Endurance outcomes: measured by 400 m walk (Bennett & Hackney, 2018) or 6-minute walk test (6MWT) (Brach et al., 2013; Day et al., 2012).
5. Physical activity (PA): measured by self-reporting (Edgren et al., 2019; Neil-Sztramko et al., 2020; Richardson et al., 2020; Siltanen et al., 2020) or performance tests (Day et al., 2012; Edgren et al., 2019; Siltanen et al., 2020).
6. Mobility outcomes: assessed using LSA (Edgren et al., 2019; Siltanen et al., 2020) or self-reported (Richardson et al., 2020).
7. Quality of life outcomes: measured by WHO Quality of Life (WHOQOL) (Edgren et al., 2019), 12-Item Short-Form Health Survey (version 2) (SF-12v2) (Manini et al., 2007), or 36-Item Short-Form Health Survey (SF-36) (Moore-Harrison et al., 2008; Richardson et al., 2008, 2020).
8. Psychological outcomes include SE (Richardson et al., 2020) and depression (Day et al., 2012, 2015; Edgren et al., 2019).

Changes in PCML outcomes

Changes in PCML outcomes as a result of the intervention were evaluated by whether there was an improved score in PCML measures and/or a decreased proportion of participants with PCML (Table 1). Although only eight studies reported the PCML results after the intervention, the findings varied regarding the outcome measures and intervention effectiveness.

Out of the six studies reporting changes in the scores of PCML measures, five studies revealed significant improvements in the intervention group's PCML scores compared to the controls (Bean et al., 2019; Brach et al., 2013; Manini et al., 2007; Moore-Harrison et al., 2008; Richardson et al., 2008). For example, Brach et al. (2013) reported that compared with the controls, participants with pre-clinical gait dysfunction receiving motor learning exercise intervention improved significantly more in gait speed (0.13 vs. 0.05 m/sec, $p = 0.008$) and motor skill (-2.2 vs. -0.89 sec, $p < 0.001$). Richardson et al. (2008) compared participants receiving detailed feedback from physiotherapists (PT)/ occupational therapists (OT) about physical function assessment results over 18 months with those who did not receive feedback in the control group. They found statistically significant group/time interactions for Fried scale (frequency subscale, $F = 3.78$, $p \leq 0.05$; modification subscale, $F = 4.58$, $p \leq 0.05$). Another study reported that changes in PCML outcomes in the intervention group compared with controls differed by measures. There were significant improvements in gait speed and self-reported difficulty climbing a flight of stairs, but not in the difficulty of walking 0.4 km (Bennett & Hackney, 2018).

Three studies assessed the impact of interventions on the percentage of participants with PCML. However, there is variation in the results across these studies (Moore-Harrison et al., 2008; Neil-Sztramko et al., 2020; Rantanen et al., 2019). One study reported that the number of participants with PCML in the intervention group (16-week supervised walking interventions) decreased significantly from 66 to 25% (Moore-Harrison et al., 2008), while another study reported that the number of participants with PCML decreased but not significantly (Rantanen et al., 2019). A study used knowledge translation as an intervention for 12 weeks and reported that the number of participants with PCML decreased in both the intervention and control groups (3.9% vs. 5.2% at the end of the study, respectively; 4.6% vs. 5% at the follow-up 3 months, respectively), but that there were no significant between-group differences at the end of the study ($p = 0.59$) or at follow-up ($p = 0.19$) (Neil-Sztramko et al., 2020).

Discussion

It is more than 20 years since Fried proposed that people in the PCML stage may particularly benefit from interventions preventing disability onset (Fried et al., 1991). However, this review was only

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able to identify 14 articles available in the PCML interventions field. Two of them are protocols, and the respective published articles were also included. The majority of the studies (9/12, 75%) were published after 2011, 10 years after the PCML concept was introduced (Fried et al., 1991), 67% of which were published over the past 5 years. This may reflect the recent increase in research interest and growth in this field. However, all studies originated from the United States, Canada, Australia, and Finland. Skewed distributions in the PCML publication could be partly the result of the research group's monolingualism, which prevented review of non-English publications. However, it also suggests that the concept of PCML needs to be better recognized and explored worldwide, as it will benefit both health and longevity (Richardson, 2020).

This review included intervention studies with a full or partial percentage of participants at PCML stages. However, the measurements used to assess PCML vary from self-report measures (e.g., Fried scale) to physical performance measures (PPMs) (e.g., CS-PFP10). These two types of measures have been shown to assess different characteristics of function in older adults, and have their own respective advantages (Babić, Bertić, Križanec, & Babić, 2020; Cavanaugh, Richardson, McCallum, & Wilhelm, 2018): PPMs are objective and tend to be reproducible, less influenced by language and education, and more reliable in assessing change over time; self-report measures are accessible, easier to apply, and sensitive to capturing very early changes in function. Furthermore, self-reported measures were associated closely with objective PPMs (Young et al., 2010). Self-reported measures can be a valid benchmark in detecting PCML in some tasks in older adults who were already disabled in other tasks (Young et al., 2010). However, the variations between PPMs and self-reported measures, with respect to administration mode and outcome reporting, limit the comparison across studies in this review. In addition, validated measurements were modified by selecting part of the tasks or adding more tasks in some studies. For example, Manini et al. (2007) added the activity of "laundry basket lift and carry" on the top of the seven activities previously used to calculate the MOD score (Manini, Cook, VanArnam, Marko, & Ploutz-Snyder, 2006); while Bennett and Hackney (2018) selected seven out of the 27 activities originally used in Fried scale. This raises the question of what task(s) should be selected to ask about for early detection of disability progression.

In this review, eight categories of outcomes were summarized as associated with PCML outcomes in the studies: physical function and disability outcomes, balance, lower extremity strength, endurance, PA, mobility, quality of life, and psychological outcomes. The physical decline in muscle strength, endurance, mobility, and balance collectively contribute to the limitation of functional capacity, which can be influenced by PA (Tomás, Galán-Mercant, Carnero, & Fernandes, 2018). The prediction of PCML on falls, adverse health outcomes, diminished quality of life, and the onset of difficulties in various tasks, not limited to activities of daily living (ADLs)/ instrumental activities of daily living (IADLs) but encompassing a broader range of activities, has been reported in both cross-sectional and longitudinal studies (Clough-Gorr et al., 2008; Fried et al., 2000; Katz, Morris, & Yelin, 2008; Wolinsky et al., 2007). PCML presents both as a risk marker associated with impairment or limitation and a mediating factor for disability progression (Weiss et al., 2007). This suggests that the rationale for PCML interventional studies extends beyond focusing solely on PCML outcomes to explore how underlying etiological factors can be modified to prevent the progression of the disease to mobility disability (Fried et al., 2001). Additionally, it emphasizes the importance of assessing and reporting associated outcomes to identify if any of the multiplicity of risk factors can be minimized through the intervention.

This review does not seek to gauge the effectiveness of rehabilitation interventions on PCML-associated outcomes, but rather to describe what associated outcomes were assessed in currently available PCML interventional studies. However, also of importance is what outcomes should be utilized in combination with PCML outcomes when exploring interventions in the pre-clinical stage, for preventing or delaying overt disability progression (Fried et al., 2001). It is noteworthy that 33 per cent (4/12) of studies in this review reported psychological outcomes. Psychological constructs/ outcomes such as lower SE, higher anxiety, and depressed mood were associated with PCML (Higgins et al., 2012; Hirvensalo et al., 2007). This can be further investigated in future studies, as such an approach may advance the use of compensatory strategies and serve as a focus for future interventions aimed at disability prevention (Higgins et al., 2012).

This review identified the types of available evidence in the PCML rehabilitation intervention literature, including exercise, education, tele-physical therapy, knowledge translation, and counselling. The effectiveness of interventions was evaluated by measuring changes in PCML scores or the percentage of participants with PCML. All five studies that used PCML scores as an outcome measure demonstrated effectiveness, showing an improved score. However, discrepancies arose in studies that assessed the percentage of participants with PCML, with only three studies available for analysis. In the study in which exercise was used as an intervention and PPM as a measurement, a significant decrease in PCML participants was observed in the intervention group. This change differed significantly when compared with the control groups. Conversely, when using a self-reported scale (i.e., Manty scale) as an outcome measurement, the decreased percentage of PCML participants in the intervention groups (counselling or Knowledge Translation intervention) either showed no significant change over time or did not differ significantly from the control groups. These discrepancies suggest the benefits of using exercise as an intervention and highlight the sensitivity of using PPM as an outcome measure. Yet, this finding must be interpreted with caution, given the heterogeneous nature of the sample, diversity of the eligibility criteria, difference in the length of the intervention and follow-up, and various PCML measures across the studies. The results need to be confirmed by a systematic review with a larger number of studies. Together these findings may inform future intervention strategies so that they can be clinically effective in disability prevention.

Future Research Directions

The mobility concepts are multifactorial and complex (Freiberger et al., 2020). Correspondingly, mobility disability may result by multiple functional declines across multiple systems (Fried et al., 2001). Therefore, a multifaceted intervention may be the most effective approach to jointly benefit older adults in the PCML stage. An example of this approach is the combination of exercise and a mobility SM program (Richardson et al., 2020). Future research should employ multifaceted interventions with different intervention components to address questions on maintaining functional competence, preventing adverse outcomes, and reducing the burden of disability in this population.

The measurements that assess PCML need to have established sensitivity to change in this population to capture the pre-clinical

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signs of functional decline. Performance-based measures are objective, quick, inexpensive, and more reliable in assessing change over time, whereas self-reported measures are sensitive to early changes in function. The use of performance-based ADL/IADL assessment independent of or in conjunction with self-report as a method of identifying pre-clinical disability in older adults was reported in a previous study (Toto, Terhorst, Rogers, & Holm, 2017). By combining both, researchers can have greater specificity in detecting incident mobility difficulty than by using either alone. In addition, self-report of functional limitation is also associated with education (Gregory et al., 2011), culture or socio-environmental differences associated with culture (Spencer, 2008), gender (Lorenz, 2009), body sensation, and coping practice that allows bodily limitations to remain unnoticed or conceals limitations from others (Lorenz, 2007, 2010). Future research using self-reported measures should also consider these factors when implementing measures.

Conclusion

This scoping review identified 14 articles focusing on PCML interventions, including exercise, education, tele-physical therapy, knowledge translation, and counselling. The review demonstrated limited published work on interventions to address PCML, especially on middle-aged populations and older adults not considered to be community dwelling. It also revealed the complexity and varieties of currently available PCML measures, which leads to the difficulty in applying a unique measure that is valid and reliable to use, and compares findings across PCML studies. This review provides preliminary evidence that rehabilitation interventions with persons with PCML may help to delay and prevent disability progression. However, because the quality of the studies was not evaluated, the findings should be interpreted cautiously.

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