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Modifiable enablers and barriers of exercise adherence in older adults with MCI/dementia using the Theoretical Domains Framework: a systematic review protocol

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4 1 **Modifiable enablers and barriers of exercise adherence in older adults with**
5 2 **MCI/dementia using the Theoretical Domains Framework: a systematic review protocol**

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31 49 **Key words:** mild cognitive impairment; dementia; exercise; adherence; factors;

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39 53 **Modifiable enablers and barriers of exercise adherence in older adults with**

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41 54 **MCI/dementia using the Theoretical Domains Framework: a systematic review protocol**

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44
45 56 **ABSTRACT**

46
47 57 **Introduction** Considering the inefficiency of pharmacological intervention, exercise as one

48
49 58 of the non-pharmacological interventions is recommended for older adults with

50
51 59 MCI/dementia and its effects have been proven by practice. However, the positive effects of

52
53 60 all exercise interventions depend highly on exercise adherence. In fact, exercise adherence is

54
55 61 not ideal from the results of previous literature among older adults with MCI/dementia. High

56
57 62 drop-out rates reduce the effect of exercise for MCI and dementia. Allowing for the current

58
59 63 studies on exercise adherence in older adults with MCI/dementia still have some deficiencies.

60
61 64 The aim of this paper is to identify the modifiable barriers and enablers of exercise adherence

62
63 65 in older adults with MCI/dementia from the perspectives of patients, carers and healthcare

professionals according to Theoretical Domains Framework(TDF) of a broad based theoretical framework for behaviour change in order to provide references for healthcare professionals developing exercise strategies and improving exercise adherence.

Methods and analysis A systematic review of qualitative and quantitative studies will be conducted. PubMed, Embase, The Cochrane Library (Cochrane Central Register of Controlled Trials), Web of Science(Science and Social Science Citation Index), China National Knowledge Infrastructure(CNKI), the Wan Fang Database and grey literature will be searched and two reviewers will screen studies according to predefined eligible criteria. Barriers and enablers will be extracted and synthesised on the basis of the Theoretical Domains Framework from perspectives of patients, carers and healthcare professionals by two independent reviewers.

Ethics and dissemination We will report this review in accordance with the PRISMA statement. This systematic review does not require ethical approval as no primary data are collected. We are going to publish our findings in a peer-reviewed journal.

PROSPERO registration number CRD42019117725.

Strengths and limitations of this study

1.To the best of our knowledge, no previous work has been carried out to systematically map and categorise modifiable enablers and barriers of exercise adherence in older adults with MCI/dementia using the Theoretical Domains Framework.

2.Our systematic review will be the first attempt to summarise the current available evidence on the insights of patients, carers and healthcare professionals.

3.We will perform an all-round search of published and grey literature with no restrictions on date, language or geographical location.

4.The main study limitation is that no meta-analysis or other statistical analysis will be performed in this review.

BACKGROUND

Description of the MCI/dementia condition

Mild cognitive impairment(MCI) is the intermediate phase between normal cognitive functioning and dementia, characterized by cognitive decline that is larger than expected considering a person's age and education, though without conspicuous interference in

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4 96 daily-life activities.¹ The published prevalence of people with MCI is approximately 10% to
5
6 97 20% worldwide that depends on the sample and the follow-up duration of studies at present.²
7
8 98 People with MCI have a heightened risk of further cognitive decline and progression to
9
10 99 dementia, it is reported that 10% to 15%, 60.5%, and 100% of patients with MCI will develop
11
12 100 full dementia within 1 year, 5 years, and 9.5 years, respectively, after initial diagnosis of
13
14 101 MCI.³ Dementia is characterized by progressive and severe cognitive decline, motor deficits
15
16 102 and/or behavioral problems causing a decline in activities of daily living (ADL).⁴ As life
17
18 103 expectancy is getting longer worldwide, the number of people affected by MCI and dementia
19
20 104 is steadily growing.⁵ According to estimates from the World Alzheimer Report, The number
21
22 105 of people with dementia is expected to dramatically increase in the coming decades, from 47
23
24 106 million in 2015 to 131.5 million by 2050.⁶ These rapidly growing numbers will have a
25
26 107 tremendous social impact, placing a high economic burden on the healthcare system.⁶⁻⁷
27
28 108 Therefore, the World Health Organization(WHO) stresses to take global action against
29
30 109 cognitive decline and dementia, encouraging governments all over the world to focus on
31
32 110 prevention, disease modifying therapies and improving health care services.⁸

33 111 Pharmacological and nonpharmacological interventions are two promising options for
34
35 112 MCI and dementia. To date, there are no definite or disease-modifying therapeutic options for
36
37 113 dementia, only the cholinesterase inhibitors, galantamine, rivastigmine, donepezil and the
38
39 114 N-methyl D-aspartate receptor antagonist memantine are approved for the symptomatic
40
41 115 therapy of cognitive symptoms in dementia so far.⁹⁻¹⁰ These drugs may initially improve
42
43 116 cognition and slow down the clinical progression of dementia but are not capable of stopping
44
45 117 the underlying pathological process of dementia, including amyloid accumulation, tau protein
46
47 118 aggregation, synaptic loss and neuronal death.¹⁰⁻¹¹ In the clinical use of drug, there still exist
48
49 119 uncertainties, for example, on their efficacy in early stages of dementia or the MCI-dementia
50
51 120 phase, when to stop them or how to monitor long-term efficacy in the individual patient and
52
53 121 long-term medication costs a large sum of money which exerts a big burden on families and
54
55 122 the whole society.¹⁰

56 123 For the treatment of MCI, as far as diagnostic uncertainty and the heterogeneous
57
58 124 underlying pathophysiological mechanisms are concerned, only limited therapies are
59
60 125 currently available.¹² There isn't any approved pharmacological treatment exist for MCI so

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4 126 far and only modest evidence for symptomatic treatment efficacy.¹³ Most results reflect not
5
6 127 only a lack of effectiveness of drug therapy but also have a negligible effect on the cognition
7
8 128 of people with MCI, for example, the cholinesterase inhibitors galantamine, this medication
9
10 129 increases the rate of death and has no effect on the conversion rate from MCI to
11
12 130 dementia.¹²⁻¹⁴ And pharmacotherapy is preferably limited to the patients with MCI who are at
13
14 131 higher risk of transition to dementia.¹⁵⁻¹⁶ Factors including limited options, medications
15
16 132 side-effects, uncertain prognosis, and inappropriate social, psychological, more economic
17
18 133 spending and ethical consequences restrict the pharmacological treatment of MCI.¹⁶
19
20 134 Therefore, there is an urgent need for more other effective treatment options for cognitive
21
22 135 symptoms. Many researches are focusing on non-pharmacological interventions that mainly
23
24 136 include cognitive intervention, exercise, music therapy, psychological intervention and diet
25
26 137 management, and etc.¹⁷⁻¹⁸ A series of studies have examined the effects of
27
28 138 non-pharmacological interventions on cognition in older adults with MCI/dementia, including
29
30 139 memory, abstraction, mental flexibility, self-control, executive functions and attention, which
31
32 140 were measured by validated and reliable instruments.¹⁸⁻¹⁹ Non-pharmacological interventions
33
34 141 have less risk than pharmacological interventions(i.e. low likelihood of contraindications or
35
36 142 problems that occur with polypharmacy).¹⁸ In this occasion, older adults may prefer
37
38 143 non-pharmacological interventions to maintain cognitive function rather than
39
40 144 pharmacological strategies with possible side effects.

41 145 As one of the major recommendations for non-pharmaceutical interventions, exercise
42
43 146 has been consistently found to be associated with a reduced risk of developing
44
45 147 dementia(regardless of its subtype)/MCI as shown in several systematic reviews and
46
47 148 meta-analyses, which also reports exercise places a positive effect on physical, cognitive,
48
49 149 functional, and behavioral outcomes for MCI and dementia.²⁰⁻²² Such improvements might
50
51 150 directly enable the person to perform daily activities including independent self-care or with
52
53 151 little assistance.

54 152 Despite these positive findings, there remain concerns that older adults with
55
56 153 MCI/dementia are physically inactive and their adherence to exercise is poor.²³⁻²⁴ Tak et al
57
58 154 showed that maintenance of participation in exercise programs in older adults with MCI is
59
60 155 low, only 25% continued exercising after the end of the 12-month RCT.²⁴ And only 19% of

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4 156 67 nursing home AD residents had high adherence to a year-long exercise program
5
6 157 (completed > two-thirds of possible exercise sessions), and 52% had low
7
8 158 adherence(completed < one third of possible sessions), mean adherence was 33.2±25.5% in
9
10 159 the whole sessions was found in Rolland's study.²³ A randomized controlled trial conducted
11
12 160 by Suttanon et al showed similar results that forty older adults with mild to moderate
13
14 161 Alzheimer's disease were randomized to a six-month home-based individually tailored
15
16 162 balance, strengthening and walking exercise programme or a six-month home-based
17
18 163 education programme(control), only fifty-eight percent of the exercise group finished the
19
20 164 programme.²⁵ Thus it can be seen that the level of adherence of older adults with
21
22 165 MCI/dementia is still not optimistic about the current situation and we need to pay more
23
24 166 attention on relevant research of exercise adherence.

25 167 **Why is it important to do this review?**

26
27 168 The positive effects of all exercise interventions depend highly on exercise adherence.²⁶ High
28
29 169 drop-out rates reduce the effect of exercise for MCI and dementia. Lowery D et al also
30
31 170 concluded that it is an essential research to identify factors influencing participation in
32
33 171 exercise in community dwelling adults with dementia for the reason that they found that only
34
35 172 30.7% achieved the prescribed frequency of the exercise intervention after they went on a
36
37 173 randomized control trial.²⁷ In order to increase MCI/dementia patients' exercise adherence
38
39 174 levels, there is a need to understand better the factors that affect exercise adherence in such
40
41 175 populations. Specifically, identifying the barriers and enablers of exercise may improve the
42
43 176 success rate of exercise implement suitable for dementia patients' care. Stubbs et al have
44
45 177 systematically reviewed the literature to establish the factors associated with exercise
46
47 178 participation in community dwelling adults with dementia, they find that increased energy
48
49 179 intake, resting metabolic rate, fat free mass, gait speed, global motor function, overall health
50
51 180 related quality of life (HRQOL), physical HRQOL, higher levels of social functioning and
52
53 181 reduced apathy were positively associated with exercise; and taking \geq four medications,
54
55 182 dizziness, lower ADL function, a history of falls, less waking hours in the day, more
56
57 183 autonomic problems and delirium were negatively associated with PA.²⁸ A more recent
58
59 184 meta-analysis further collected and synthesized the evidence on known barriers and enablers
60
185 to adherence of institutionalized older people living with dementia to group exercise,

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4 186 including three thematic categories, bio-medical reasons and mental wellbeing and physical
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6 187 ability; relationship dynamics; and socioeconomic reasons.²⁹

7
8 188 However, the current studies on exercise adherence in older adults with MCI/dementia
9
10 189 still have the following deficiencies:

11 190 ***(1) The lack of theory framework***

12
13 191 Previous studies on enablers and barriers of exercise adherence in older adults with
14
15 192 MCI/dementia lacked the support or elaboration of behavioral theory framework. Behavioral
16
17 193 theory provides alongside potential determinants (or constructs)—a structure and context for
18
19 194 thinking logically about these determinants and their relationships.³⁰ Applying a behavioral
20
21 195 theoretical framework to assessing barriers and enablers can effectively help develop tailored
22
23 196 informed strategies to support the effective implementation of evidence-based practices.³¹ In
24
25 197 this study, we will rely on Theoretical Domains Framework(TDF) to classify enablers and
26
27 198 barriers of exercise adherence in older adults with MCI/dementia. The TDF is a
28
29 199 comprehensive framework that synthesizes a number of behavior change theories. It was first
30
31 200 developed in 2005 with 12 domains and 128 constructs, and in 2012, its validity was
32
33 201 reevaluated, and a refined version of the TDF was proposed with 14 domains and 84
34
35 202 constructs.³²⁻³³ TDF has been successfully used in many medical systems for clinical
36
37 203 performance improvement to explain practical issues and provide theory-informed guide for
38
39 204 further effective interventions.³⁴⁻³⁶ The TDF therefore offers an appropriate theory to support
40
41 205 an evidence synthesis of drivers of adherence which can be used to facilitate the design and
42
43 206 development of targeted exercise interventions.

44 207 ***(2) Little know about the barriers and enablers to targeted exercise amongst older adults***
45
46 208 ***with MCI***

47
48 209 MCI and dementia are two different stages of the cognitive impairment disease. The
49
50 210 psychosocial characteristics of the patients may exist differences in exercise adherence
51
52 211 theoretically. To the best of our knowledge, the factors associated with exercise adherence of
53
54 212 older adults with MCI only are reported by a small number of clinical studies, and no author
55
56 213 has systematically reviewed the related factors.²⁴

57
58 214 ***(3) The lack of systematic research on the modifiable factors that impact exercise***
59
60 215 ***adherence in older adults with MCI/dementia***

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4 216 We cannot change behavior of exercise adherence resulting from nonmodifiable factors
5
6 217 such as family history, sex and age. Identification of such modifiable factors and assessing
7
8 218 which factors improve or deteriorate exercise adherence is a vital approach to designing
9
10 219 interventions. This information would serve as a reminder that provides guidance for medical
11
12 220 staff refining target population and intervention methods in theory and then contributing to
13
14 221 the development of adherence-oriented programmes of exercise intervention in practice.

15 222 ***(4) The absence of research on discussing adherence from different people's insights***

16
17 223 The insights of patients, carers and healthcare professionals often differ regarding the
18
19 224 barriers and enablers of exercise adherence due to differing priorities and knowledge of the
20
21 225 situation.³⁷⁻³⁹ "Carers" are used to refer to the primary carer for someone diagnosed with
22
23 226 MCI/dementia, the family members of patients or hired the nursing staff are both included,
24
25 227 they are primarily responsible for patients' food and accommodation and may have a better
26
27 228 understanding of living environment factors of patients.³⁸ Older adults especially with
28
29 229 dementia often need help from their carers to complete many of their daily activities, it is
30
31 230 expected that carers would play an important role in exercise intervention.³⁹ Therefore,
32
33 231 opinions from carers should taken into account. Healthcare professionals include physicians,
34
35 232 nurses, clinical psychologists, the manager or administrator of nursing home, experts in
36
37 233 exercise intervention, etc.^{37, 40} They are mainly in charge of the whole exercise intervention
38
39 234 program who may pay more attention to the methodological factors of exercise, and previous
40
41 235 studies also have highlighted the importance of support from health professionals to
42
43 236 encourage people to take part in an exercise program.⁴¹⁻⁴² Currently the barriers and enablers
44
45 237 of exercise adherence among older adults with MCI/dementia from different people's
46
47 238 perspectives have not been studied, so that the information about the barriers and enablers
48
49 239 may lack for more comprehensive information which will not be good for generate more
50
51 240 generalisable theories.

52 241 All those discussed above show that an overall understanding of the modifiable barriers
53
54 242 and enablers to exercise intervention from the perspectives of patients, carers and healthcare
55
56 243 professionals, synthesised according to TDF of a broad based theoretical framework for
57
58 244 behaviour change, is needed. Thus we aim to conduct a systematic review to collect and
59
60 245 synthesize the available evidence on modifiable barriers and enablers of exercise adherence

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4 246 among older adults with MCI/dementia, and further classify them into the domains of the
5
6 247 TDF to inform clinical practice of healthcare professionals recommending and prescribing
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8 248 exercise, and to develop strategies that promote the behavior change needed in patients for
9
10 249 long-term exercise adherence.

11 250 **METHODS/DESIGN**

12
13 251 This protocol is written in accordance with the recommendation of the PRISMA-P
14
15 252 Elaboration and Explanation document.⁴³ We plan to complete the systematic review with an
16
17 253 expected completion date of May 31, 2020, This review has been registered with the
18
19 254 international database of prospectively registered systematic reviews in health and social
20
21 255 care(PROSPERO; registration number CRD42019117725).

22 256 **Eligibility criteria**

23 257 **Types of participants**

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25
26
27 258 Eligible studies will include any type of MCI/dementia. No limitations will be placed on the
28
29 259 severity of MCI/dementia, length of time since diagnosis. No restrictions will be placed on
30
31 260 severity of depression, anxiety, psychological distress or mental health-related quality of life.
32
33 261 These individuals will be included as follows:

34
35 262 (1) The people aged 65 years or older.

36
37 263 (2) For dementia: Including studies involving people diagnosed with any type of dementia,
38
39 264 according to the criteria in the Diagnostic and Statistical Manual of Mental Disorders, Third
40
41 265 Edition(DSM-3), Fourth Edition(DSM-4), Text Revision(DSMIV-TR), or Fifth
42
43 266 Edition(DSM-5), International Classification of Diseases, Tenth Revision(ICD-10), Mini
44
45 267 Mental State Examination(MMSE)/Montreal Cognitive Assessment(MOCA) score available,
46
47 268 or other alternative validated diagnostic criteria, or recorded in medical records.

48
49 269 (3) For MCI: Including studies involving people diagnosed with any type of MCI according
50
51 270 to the criteria in the DSM-5 criteria, Petersen's criteria, alternative validated diagnostic
52
53 271 criteria, MMSE/MOCA score available, or where recorded in medical records.

54
55 272 (4) These will be excluded: Patients who have severe visual or auditory impairment, serious
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57 273 medical conditions in major organs(heart, lung or kidney), illnesses affecting mobility or are
58
59 274 unable to accept assessments or interventions that are required in this study for any reasons.

60 275 **Types of exercise intervention**

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4 276 This systematic review will include all studies involving any type of exercise. Exercise
5
6 277 intervention is defined as a type of physical activity that is planned, structured and repeated
7
8 278 over a period of time.⁴⁴ The eligible exercise can be categorized into resistance training,
9
10 279 aerobic exercise, combined exercise and other types of training. In addition, all organizational
11
12 280 forms of intervention(individual, group, or mixed) are eligible for inclusion. And supportive
13
14 281 strategies(face to face, telephone, email) will be eligible for inclusion. There will be no
15
16 282 limitations about the professional background of the person sustaining the exercise
17
18 283 intervention, additionally unsustained(self-guided/self-administered) interventions will also
19
20 284 be eligible for inclusion.

21 285 **Type of setting**

22
23 286 Studies in any setting where exercise intervention is conducted including healthcare
24
25 287 institutions, community, home or in any geographical setting globally will be considered for
26
27 288 inclusion.

29 289 **Types of outcome measures**

30
31 290 Outcomes of studies that report barriers and enablers influencing uptake and/or maintenance
32
33 291 of exercise in older adults with MCI/dementia will be included.

35 292 **Types of studies**

36
37 293 The searches are not limited to specific study design. Hence, all study designs using
38
39 294 qualitative or quantitative methodologies will be included in the review. The papers will be
40
41 295 categorized by study design using the following categories: randomized-controlled trial,
42
43 296 quasi-controlled trial, cohort study, cross-sectional study, and qualitative study.

44 297 **Theme of studies**

45
46 298 Studies will be included if

- 47
48 299 (1) They directly explore the factors/barriers/enablers/motivation that correspond to
49
50 300 engagement in exercise;
51
52 301 (2) They directly address or focus on any aspect of the experience or perceptions of older
53
54 302 adults with MCI/dementia regarding exercise and mentioning exercise adherence enough to
55
56 303 answer our question.

58 304 **The language of studies**

59
60 305 Studies will be no language restrictions.

1
2
3
4 306 **Publication year**

5 307 From 1 January 1990 to the date of the searches.

6
7 308 **Information sources**

8
9 309 The following electronic bibliographic databases: PubMed, Embase, The Cochrane Library,
10 310 Web of Science, China National Knowledge Infrastructure(CNKI), and the Wan Fang
11 311 Database will be searched from 1 January 1990 to the date of the searches about Human
12 312 studies. In order to improve the completeness of the literature, grey literature sources will be
13 313 considered. We will further check the reference list of the included studies and relevant
14 314 reviews.

15
16
17 315 **Search strategy**

18 316 Based on key terms from previous literature reviews and Medical Subject Headings,
19 317 Our search will use both the medical subject headings and text word and will combine
20 318 concepts for the influencing factors of adherence, Our search strategy will consist of three
21 319 parameters: disease(MCI/dementia), intervention(exercise) and outcome(adherence). The
22 320 search strategy we will use for the retrieval of reports of trials from PubMed is summarized in
23 321 Table 1. The search strategy will be modified as necessary for other databases.
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25
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37 **Table 1** The search strategy of PubMed

Number	Search items
1	Dementia OR Cognitive Dysfunction OR Mild Cognitive Impairment* OR MCI OR VCI OR AAMI OR SMC OR ACMI OR ARCD OR CIND OR (nMCI or aMCI or mMCI or MCIa) OR MCD OR AACD OR MNCD OR Mild Neurocognitive Disorder* OR cogn* OR Cognitive impairment OR Alzheimer OR AD OR Alzheimer's disease
2	Ageing OR aging OR Elderly OR "Aged,80 and over" OR "Old* age*" OR "middle age*" OR "old* adults" OR senior* OR senior citizens OR old people OR old person
3	Exercise OR Physical activit* OR Treadmill training OR Balance OR Strength OR Endurance OR Attention training sport* OR jogging OR physical therapy OR physiotherapy OR exercise* OR fitness OR rehabilitation OR flexibility OR motor activit* OR leisure activit* OR strength OR balance OR aerobic* OR physical* OR

1
2
3
4 training OR bicycling OR cycling OR swim* OR gym* OR walk* OR danc* OR yoga
5
6 OR joga OR tai chi OR tai ji OR taichi OR Taijiquan OR tai-chi OR pilates OR
7
8 movement OR recovery of function OR inactivit* OR sedentary OR physical inactivit*
9
10 OR occupational therapy OR physical stimulation OR physical education OR physical
11
12 medicine OR resistance OR mind-body OR Mind Body

13
14 4 barrier* OR enabler* OR motivators OR facilitators OR implementation OR adherence
15
16 OR compliance OR support OR selfefficacy OR self-efficacy OR self efficacy OR
17
18 self-efficiency OR motivation OR experience* OR perspective* OR factor* OR
19
20 attendance OR predictor*OR preference*

21
22 5 1 and 2 and 3 and 4

23
24 323

25
26 324 **The selection process of studies**

27
28 325 The study selection process will be reported according to the PRISMA flowchart.⁴⁵ First,
29
30 326 removing duplicates using the reference manager software Endnote X7. Then titles and
31
32 327 abstracts of articles will be screened, selected full-text articles will be assessed for eligibility
33
34 328 and data will be extracted by two independent researchers(HY and YX C), disagreement will
35
36 329 be solved by discussion. A third researcher (CX G) will be invited in case of persistent
37
38 330 contradiction. In the final, two other authors (HQ C and JW) will assess potentially eligible
39
40 331 full-text studies to make sure if they meet the criteria set for inclusion.

41
42 332 **Data items and data abstraction process**

43
44 333 All data will be extracted into an Excel file. Data extraction will be undertaken independently
45
46 334 by two researchers(XT Z and LN W). Any disagreement between the two researchers will be
47
48 335 resolved through further discussion and adjudication by a third reviewer(J W). For each study
49
50 336 that meet the inclusion criteria, It is anticipated that we will extract the following
51
52 337 information:

53
54 338 **(1) Bibliographic information:** the journal name, title, first author's name, publication year,
55
56 339 language of the study, country of corresponding author;

57
58 340 **(2) Study design:** specific type of study, exercise intervention technique, duration, outcomes
59
60 341 measured, instruments used to measure them, data collection methods, sample size, quality of

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4 342 study.

5 343 **(3) Participants data:** type of disease, disease screening tools/diagnostic tools, setting,
6
7 344 inclusion and exclusion criteria, sample size, sociodemographic characteristics(eg. age,
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9 345 ethnicity, country).

10
11 346 **(4) Outcomes:** definition and rate of adherence, influencing factors of adherence.

12 13 347 **Risk of bias (quality) assessment and meta-bias**

14
15 348 Two independent reviewers rigorously will assess the quality of each paper. The
16
17 349 Newcastle-Ottawa Scale (NOS) will be used to assess the quality of cohort articles.⁴⁶
18
19 350 Cross-sectional studies will be examined using the Agency for Healthcare Research and
20
21 351 Quality (AHRQ).⁴⁷ Randomized controlled trials will be assessed according to PEDpro.⁴⁸ The
22
23 352 Joanna Briggs Institute (JBI) critical appraisal checklist will be used to assess the quality of
24
25 353 quasi-randomized controlled trials.⁴⁹ Qualitative research will adopt the tool that JBI made
26
27 354 critical appraisal tools for qualitative research in 2016.⁵⁰

28 29 355 **Data synthesis and analysis**

30
31 356 This review will synthesize all related qualitative and quantitative literature. Characteristics
32
33 357 and outcomes of each study will be summarized and presented in an evidence table. We will
34
35 358 use the statistical software package NVivo V.12 to help us manage the extract useful
36
37 359 information and we will classify three themes from the perspective of the patient perspective,
38
39 360 carers perspective and healthcare professional perspective to conform the aim of our study.
40
41 361 We will divide each subject theme into two subthemes(modified barriers and enablers), and
42
43 362 for each subtheme we will create 15 domains(14 TDF domains plus 'Others'). Then, the
44
45 363 identified information from every article will be classified into the fourteen subcomponents
46
47 364 of the TDF plus 'Others'. The whole process of data synthesis will be conducted by one
48
49 365 researcher(XT Z) and checked by a second independent researcher with experience in the
50
51 366 thematic analysis(HQ C) to enhance credibility.

52 53 367 **DISCUSSION**

54
55 368 This systematic review will be the first try that map modifiable barriers and enablers to
56
57 369 exercise for older adults with MCI/dementia to the domains of the TDF. There are three
58
59 370 major advantages of adopting TDF, and they are as follows:

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371 First of all, in theory, TDF is a comprehensive framework that synthesizes many behavior

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4 372 change theories, which lower the risks of missing relevant theoretical constructs or including
5
6 373 irrelevant ones, so it can be used for summarizing the related factors of exercise adherence
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8 374 reported in the literature from all angles. The next, from a practical point of view, the
9
10 375 constructs comprising the TDF provide a basis from which to create an understanding of the
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12 376 behaviours associated with adherence of exercise and help clinical staff make appropriate
13
14 377 improvement strategies to facilitate behaviour change for exercise adherence.³³ Last but not
15
16 378 the least, the usefulness of TDF has been confirmed in various medical practice gradually. In
17
18 379 Denmark, TDF has been applied into understanding factors influencing behavior in the
19
20 380 implementation of tobacco cessation programmes and counselling guidelines amongst dental
21
22 381 providers.³⁴ In Canada, it has been applied into assessing barriers to change for planning
23
24 382 health care quality interventions.³⁵ In Australia, TDF has been applied into identifying what
25
26 383 are the barriers and enablers of referral, uptake, attendance and completion of pulmonary
27
28 384 rehabilitation for people with chronic obstructive pulmonary disease (COPD) and the results
29
30 385 provides a framework for identifying target areas for intervention.³⁶ In view of the
31
32 386 effectiveness of TDF, it therefore offers an appropriate theory to synthesize extensive barriers
33
34 387 and enablers reported in single studies and provide a deeper insight of the influences on
35
36 388 evidence-based behavior change means. Findings based on the theory can be used to inform
37
38 389 the development of effective adherence interventions to assist practitioners in choosing the
39
40 390 most suitable evidence-based exercise programs in clinical settings accordingly.
41
42 391 In addition, this review will synthesise and report qualitative and quantitative data about
43
44 392 exercise adherence from the perspective of patients, carers and healthcare professional. The
45
46 393 results will help understand common influencing factors to focus on how to modify barriers
47
48 394 best and enhance enablers to increase the use and appeal of the exercise intervention. And it
49
50 395 will facilitate effective access to care and treatment to help people with MCI/dementia have a
51
52 396 wider adoption to exercise intervention. In the meantime, it would have substantial
53
54 397 implications for researchers, clinicians, and policymakers about how to provide a better,
55
56 398 specialist care for older adults with MCI/dementia.

399 **Amendments**

58 400 If we need to amend this protocol, the date of each amendment will be accompanied by a
59
60 401 description of the change and the rationale.

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4 402 **Patient and public involvement**

5 403 Patients and public were not involved at this stage of the project.

7 404 **Ethical issues**

9 405 The systematic review is a retrospective study, using data that are publicly available. As no
11 406 primary data collection will be undertaken and does not require a formal ethical assessment
13 407 and no informed consent are needed.

15 408 **ACKNOWLEDGMENTS**

17 409 **Conflict of interest**

19 410 All authors declare that we have no conflicts of interest.

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29 415 of the study nor in the writing of protocol.

31 416 **Contributors**

33 417 All authors contributed to the development of the study design and search strategy. XT Z and
35 418 LN W designed the study and wrote the protocol. XT Z and H Y wrote the search strategy. H
37 419 Y, YX C and CX G screened the literature. WJ and HQ C checked selected article. All
39 420 authors provided feedback and approved the final protocol.

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For peer review only

Reporting checklist for protocol of a systematic review.

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Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the PRISMA-Preporting guidelines, and cite them as:

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	Reporting Item	Page Number
Title		
Identification	#1a Identify the report as a protocol of a systematic review	1
Update	#1b If the protocol is for an update of a previous systematic review, identify as such	n/a not an update
Registration		
	#2 If registered, provide the name of the registry (such as PROSPERO) and registration number	1
Authors		
Contact	#3a Provide name, institutional affiliation, e-mail address of all protocol authors; provide physical mailing address of corresponding author	1
Contribution	#3b Describe contributions of protocol authors and identify the guarantor of the review	20
Amendments		
	#4 If the protocol represents an amendment of a previously completed or published protocol, identify as such and list changes; otherwise, state plan for documenting important protocol amendments	19
Support		

1	Sources	#5a	Indicate sources of financial or other support for the review	n/a not included
2				
3	Sponsor	#5b	Provide name for the review funder and / or sponsor	20
4				
5	Role of sponsor or	#5c	Describe roles of funder(s), sponsor(s), and / or institution(s), if any, in developing	20
6	funder		the protocol	
7				
8				
9	Introduction			
10				
11	Rationale	#6	Describe the rationale for the review in the context of what is already known	4-11
12				
13	Objectives	#7	Provide an explicit statement of the question(s) the review will address with	11
14			reference to participants, interventions, comparators, and outcomes (PICO)	
15				
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18	Methods			
19				
20	Eligibility criteria	#8	Specify the study characteristics (such as PICO, study design, setting, time frame)	12
21			and report characteristics (such as years considered, language, publication status)	
22			to be used as criteria for eligibility for the review	
23				
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25				
26	Information sources	#9	Describe all intended information sources (such as electronic databases, contact	14
27			with study authors, trial registers or other grey literature sources) with planned	
28			dates of coverage	
29				
30				
31	Search strategy	#10	Present draft of search strategy to be used for at least one electronic database,	15
32			including planned limits, such that it could be repeated	
33				
34				
35	Study records - data	#11a	Describe the mechanism(s) that will be used to manage records and data	17
36	management		throughout the review	
37				
38				
39	Study records -	#11b	State the process that will be used for selecting studies (such as two independent	16
40	selection process		reviewers) through each phase of the review (that is, screening, eligibility and	
41			inclusion in meta-analysis)	
42				
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44				
45	Study records - data	#11c	Describe planned method of extracting data from reports (such as piloting forms,	17
46	collection process		done independently, in duplicate), any processes for obtaining and confirming data	
47			from investigators	
48				
49				
50	Data items	#12	List and define all variables for which data will be sought (such as PICO items,	16
51			funding sources), any pre-planned data assumptions and simplifications	
52				
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54	Outcomes and	#13	List and define all outcomes for which data will be sought, including prioritization	17
55	prioritization		of main and additional outcomes, with rationale	
56				
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58	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias of individual studies,	17
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individual studies		including whether this will be done at the outcome or study level, or both; state how this information will be used in data synthesis	
Data synthesis	#15a	Describe criteria under which study data will be quantitatively synthesised	n/a no meta-analysis or other statistical analysis
Data synthesis	#15b	If data are appropriate for quantitative synthesis, describe planned summary measures, methods of handling data and methods of combining data from studies, including any planned exploration of consistency (such as I ² , Kendall's T)	n/a no meta-analysis or other statistical analysis
Data synthesis	#15c	Describe any proposed additional analyses (such as sensitivity or subgroup analyses, meta-regression)	n/a no meta-analysis or other statistical analysis
Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the type of summary planned	20
Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es) (such as publication bias across studies, selective reporting within studies)	n/a no meta-analysis or other statistical analysis
Confidence in cumulative evidence	#17	Describe how the strength of the body of evidence will be assessed (such as GRADE)	n/a

Notes:

- 1b: n/a not an update
- 5a: n/a not included
- 15a: n/a no meta-analysis or other statistical analysis
- 15b: n/a no meta-analysis or other statistical analysis
- 15c: n/a no meta-analysis or other statistical analysis
- 16: n/a no meta-analysis or other statistical analysis The PRISMA-P checklist is distributed under the terms of the Creative Commons Attribution License CC-BY 4.0. This checklist was completed on 22. September 2019 using <https://www.goodreports.org/>, a tool made by the [EQUATOR Network](#) in collaboration with [Penelope.ai](#)

BMJ Open

Modifiable enablers and barriers of exercise adherence in older adults with MCI/dementia using the Theoretical Domains Framework: a systematic review protocol

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Mental health, Geriatric medicine, Nursing
Keywords:	mild cognitive impairment, Dementia < NEUROLOGY, exercise, adherence, factors

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4 1 **Modifiable enablers and barriers of exercise adherence in older adults with**
5 2 **MCI/dementia using the Theoretical Domains Framework: a systematic review protocol**

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66 **Modifiable enablers and barriers of exercise adherence in older adults with**
67 **MCI/dementia using the Theoretical Domains Framework: a systematic review protocol**

68 **ABSTRACT**

69 **Introduction** As one of the non-pharmacological interventions, exercise has a good effect on
70 older adults with mild cognitive impairment (MCI)/dementia. Exercise adherence is not ideal
71 among older adults with MCI/dementia at present. Allowing for the current studies on
72 exercise adherence in older adults with MCI/dementia still have some deficiencies. The aim
73 of this paper is to: (1) identify the modifiable barriers and enablers of exercise adherence in
74 older adults with MCI/dementia from the perspectives of patients, caregivers and healthcare
75 professionals. (2) use the Theoretical Domains Framework (TDF) to organize the identified
76 factors of exercise adherence among included studies.

77 **Methods and analysis** A systematic review will be developed including qualitative and
78 quantitative studies. PubMed, Embase, The Cochrane Library, Web of Science, China
79 National Knowledge Infrastructure (CNKI), the Wan Fang Database and grey literature will
80 be searched between January 1990 and February 2020. We will identify peer-reviewed
81 publications which examined enablers and barriers of exercise adherence. Searches will no
82 limitation in language publications using search terms related to exercise interventions,
83 adherence and dementia/MCI. Titles, abstracts and full-text papers will be screened by two
84 independent reviewers according to the predetermined inclusion and exclusion criteria. We
85 will use the statistical software Nvivo.12 to manage the information. The Theoretical
86 Domains Framework will be used as an a priori 'framework' to synthesize extracted
87 information in this study. We will map the literature identified modifiable barriers and
88 enablers to the domains of TDF.

89 **Ethics and dissemination** This review will summarize modifiable enablers and barriers of
90 exercise adherence in older adults with MCI/dementia for the first time. Ethical approval is
91 not required as no primary data are collected. We are going to disseminate our findings to the
92 scientific and medical community in peer-reviewed journals. The review findings will
93 facilitate effective access to care and treatment to help older adults with MCI/dementia have a

94 broader adoption to exercise.

95 **PROSPERO registration number CRD42019117725**

96 **Strengths and limitations of this study**

- 97 1. To the best of our knowledge, previous work didn't systematically map and categorize
- 98 modifiable enablers and barriers of exercise adherence about older adults with MCI/dementia
- 99 using the Theoretical Domains Framework.
- 100 2. Our systematic review will be the first attempt to summarize the currently available
- 101 evidence on the insights of patients, caregivers and health care professionals.
- 102 3. We will perform an all-round search of published and grey literature with no restrictions on
- 103 language and geographical location.
- 104 4. The main limitation of the study is that no meta-analysis or other statistical analysis will be
- 105 performed in this review.

106 **BACKGROUND**

107 **Description of the MCI/dementia condition**

108 Mild Cognitive Impairment (MCI) is the intermediate phase between normal cognitive
109 function and dementia, characterized by a delay in cognitive decline that is larger than
110 expected considering a person's age and education, though without marked interference in
111 daily-life activities.¹ The published prevalence of people with MCI is approximately 10% to
112 20% worldwide depending on the sample and the follow-up duration of studies.² People with
113 MCI have a heightened risk of further cognitive decline and progression to dementia. It is
114 reported that 10% to 15%, 60.5%, and 100% of people with MCI may develop full dementia
115 within 1 year, 5 years, and 9.5 years, respectively, after initial diagnosis of MCI.³ Dementia is
116 characterized by progressive and severe cognitive decline, motor deficits with or without
117 behavioural problems causing a decrease in activities of daily living (ADL).⁴ As life
118 expectancy is getting longer worldwide, the number of people affected by MCI and dementia
119 is steadily growing.⁵ According to estimates from the World Alzheimer Report, the number
120 of people with dementia will dramatically increase in the coming decades, from 47 million in
121 2015 to 131.5 million by 2050.⁶ These rapidly growing numbers will have a tremendous
122 social impact, placing a high economic burden on the healthcare system.⁶⁻⁷

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4 123 To date, there are no definite or disease-modifying therapeutic options for dementia and
5
6 124 MCI. For the pharmacological interventions of dementia and MCI, these drugs may initially
7
8 125 improve cognition and slow down the clinical progression of dementia/MCI but are not
9
10 126 capable of stopping the underlying pathological process of disease, including amyloid
11
12 127 accumulation, tau protein aggregation, synaptic loss and neuronal death.⁸⁻⁹ Besides, there are
13
14 128 uncertainties concerning the use of these medications, for example, on their efficacy in early
15
16 129 stages of dementia or the MCI-dementia phase, when to stop them or how to monitor
17
18 130 long-term effectiveness in the individual older adults with MCI/dementia.⁸ Because of this,
19
20 131 many researchers are focusing on non-pharmacological interventions. As one of the
21
22 132 significant recommendations for non-pharmaceutical interventions, exercise has been proved
23
24 133 to be associated with a reduced risk of developing MCI/dementia. Exercise (aerobic training,
25
26 134 resistance training and mind-body exercise, etc.) is a promising strategy for preventing or
27
28 135 delaying cognitive decline, and its salutary effects on cognitive function have been
29
30 136 demonstrated in animal models and in a growing number of clinical studies of older adults
31
32 137 with MCI/dementia.¹⁰⁻¹²

33 138 Despite these positive findings, there remain concerns that older adults with
34
35 139 MCI/dementia are physically inactive and their adherence to exercise is poor.¹³⁻¹⁴ Tak et al.
36
37 140 showed that maintenance of participation in exercise programs in older adults with MCI is
38
39 141 low, only 25% continued applying after the end of the 12-month randomized controlled trial
40
41 142 (RCT).¹⁴ It was found in Rolland's study that 19% of the individual with dementia completed
42
43 143 more than two-thirds possible exercise sessions in a year-long trial.¹³ 52% of participants just
44
45 144 completed less than one-third of possible practices, mean adherence was 33.2±25.5% in the
46
47 145 whole sessions.¹³ Thus it can be seen that the level of exercise adherence of older adults with
48
49 146 MCI/dementia was still not optimistic about the situation of adherence and we would need
50
51 147 more attention on relevant researches of exercise adherence.

52 148 **The significance for doing this review**

53
54 149 The positive effects of all exercise interventions depend highly on exercise adherence.¹⁵
55
56 150 Lowery D et al. also conclude that it is essential to identify factors influencing the
57
58 151 participation among older adults with dementia in the community since only 30.7%
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4 152 participants have achieved the prescribed frequency of the exercise in their research.¹⁶ In
5
6 153 order to increase exercise adherence levels of older adults with MCI/dementia, there is a need
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8 154 to understand better the factors that affect exercise adherence in such populations.
9
10 155 Specifically, identifying the barriers and enablers of exercise is beneficial to improve the
11
12 156 success rate of exercise implement which will promote the rehabilitation for older adults with
13
14 157 dementia. Some previous studies have established the factors associated with exercise
15
16 158 participation in community-dwelling adults with dementia, including increased energy intake,
17
18 159 resting metabolic rate, fat-free mass, gait speed, taking \geq four medications, dizziness, lower
19
20 160 ADL function, a history of falls, delirium and so on.¹⁷⁻¹⁸

21 161 However, the current studies on exercise adherence in older adults with MCI/dementia
22
23 162 still have the following deficiencies:

24
25 163 ***(1) The absence of research on discussing adherence from different people's insights***

26
27 164 The insights of patients, caregivers and health care professionals often differ regarding the
28
29 165 barriers and enablers of exercise adherence due to differing priorities and knowledge of the
30
31 166 situation.¹⁹⁻²⁶ For patients, the complicity of symptoms can make it more difficult for older
32
33 167 adults with MCI/dementia to participate in exercise programs. Older adults with
34
35 168 dementia/MCI can usually express their views and preferences about what is important to
36
37 169 them when exercising and it is morally and ethically necessary to consider those views.¹⁹⁻²⁰ In
38
39 170 comparison to caring for older adults with normal cognitive function, those caregivers taking
40
41 171 care of older adults with MCI/dementia face a substantially higher burden due to changes that
42
43 172 are typically associated with dementia.²¹⁻²² Relatively little is known on how caregivers of
44
45 173 older adults with MCI/dementia manage their support arrangements, which strategies they
46
47 174 follow and which structures are perceived as helpful or obstructive in exercise.²²⁻²³ Therefore,
48
49 175 opinions from caregivers should be taken into account. Furthermore, previous studies also
50
51 176 highlighted the importance of support from health care professionals to encourage older
52
53 177 adults with MCI/dementia to take part in exercise.²⁴⁻²⁵ The research has shown that
54
55 178 participants' adherence to exercise is improved when the instructions they receive are specific
56
57 179 and understandable from health care professionals.²⁶ In the meantime, many health care
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59 180 professionals were also concerned about participants' ability to access exercise programs.^{14,25}

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4 181 Caregivers may be a bridge to follow the advice from health care professionals and to
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6 182 supervise older adults with MCI/dementia exercise better. Teamwork and collaboration to
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8 183 improve exercise adherence among patients, caregivers and health care professionals become
9
10 184 paramount. These findings can inform future interventions to make them more meaningful
11
12 185 for this population. Currently, the barriers and enablers of exercise adherence among older
13
14 186 adults with MCI/dementia from different people's perspectives have not been studied.

15 187 ***(2) The lack of theory framework***

17 188 Previous studies on enablers and barriers of exercise adherence in older adults with
18
19 189 MCI/dementia lacked the support or elaboration of behavioural theory framework.
20
21 190 Behavioural theory can provide potential determinants and a corresponding structure for
22
23 191 thinking logically about these determinants and their relationships.²⁷ Applying a behavioural
24
25 192 theoretical framework for assessing barriers and enablers can effectively help develop
26
27 193 tailored informed strategies to support the effective implementation of evidence-based
28
29 194 practices.²⁸ In this study, we will rely on Theoretical Domains Framework (TDF) to classify
30
31 195 enablers and barriers of exercise adherence in older adults with MCI/dementia. The TDF is a
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33 196 comprehensive framework that synthesizes many behaviour change theories. It was first
34
35 197 developed in 2005 with 12 domains and 128 constructs, and its validity was reevaluated in
36
37 198 2012 with a refined version including 14 domains and 84 constructs.²⁹⁻³⁰ This framework
38
39 199 offers an appropriate structure for supporting an evidence synthesis of barriers and enablers
40
41 200 as it will help these factors to be linked to evidence-based behaviour change techniques. The
42
43 201 TDF has been successfully used in many medical systems to assess barriers and facilitators
44
45 202 about practical issues and provide a theory-informed guide for further effective
46
47 203 interventions.³¹⁻³³ Therefore, the constructs of TDF may provide a basis to help to understand
48
49 204 the barriers and facilitators of exercise adherence of older adults with MCI/dementia.

50 205 ***(3) The lack of systematic research on the modifiable factors that impact exercise***
51
52 206 ***adherence in older adults with MCI/dementia***

54 207 It is recognized that the barriers and enablers to targeted exercise amongst older adults with
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56 208 MCI/dementia are multifactorial.¹⁴⁻¹⁸ Furthermore, these factors are partly unmodifiable or
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58 209 unavoidable that is difficult for us to change (e.g. family history, sex and age). Identification
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4 210 of such modifiable factors and assessing which factors improve or deteriorate exercise
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6 211 adherence is a vital approach to design interventions. This information would serve as a
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8 212 reminder that guides medical staff in refining target population and intervention methods
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10 213 theoretically and then contributing to the development of adherence-oriented programs in
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12 214 practice. Therefore, we first attempt to identify primary research findings of modifiable
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14 215 barriers and enablers that may help to design target interventions to improve their overall
15
16 216 effectiveness.

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18 217 As summarized in the above, they all show that an overall understanding of the
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20 218 modifiable barriers and enablers to exercise intervention from the perspectives of patients,
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22 219 caregivers and healthcare professionals, synthesized according to a broad-based theoretical
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24 220 framework for behaviour change, is needed. Thus we aim to conduct a systematic review to
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26 221 collect and synthesize the available evidence on modifiable barriers and enablers of exercise
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28 222 adherence among older adults with MCI/dementia. Then we can further classify them into the
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30 223 domains of the TDF to inform clinical practise for recommending and prescribing exercise
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32 224 and to develop strategies for long-term exercise adherence.

33 225 **METHODS/DESIGN**

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35 226 This protocol is written following the recommendation of the Preferred Reporting Items for
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37 227 Systematic Review and Meta-analysis Protocols (PRISMA-P).³⁴ We plan to complete the
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39 228 systematic review with an expected completion date of October 31, 2020. This review has
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41 229 been registered with the international database of prospectively registered systematic reviews
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43 230 in health and social care (PROSPERO; registration number CRD42019117725).

44 231 **Eligibility criteria**

45 232 **Types of participants**

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48 233 Eligible studies will include any type of MCI/dementia. No limitations will be placed on the
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50 234 severity of MCI/dementia, length of time since diagnosis. No restrictions will be placed on
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52 235 the severity of depression, anxiety, psychological distress or mental health-related quality of
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54 236 life. These individuals will be included as follows:

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56 237 (1) The people aged 65 years or older.

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58 238 (2) For dementia: Including studies involving people diagnosed with any type of dementia,
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4 239 according to the criteria in the Diagnostic and Statistical Manual of Mental Disorders, Third
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6 240 Edition (DSM-3), Fourth Edition (DSM-4), Text Revision (DSMIV-TR), Fifth Edition
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8 241 (DSM-5), International Classification of Diseases, Tenth Revision (ICD-10), Mini-Mental
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10 242 State Examination (MMSE)/Montreal Cognitive Assessment (MOCA) score available, other
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12 243 alternative validated diagnostic criteria or recorded in medical records.

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14 244 (3) For MCI: Including studies involving people diagnosed with any type of MCI according
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16 245 to the criteria in the DSM-5 criteria, Petersen's criteria, an alternative validated diagnostic
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18 246 criteria, MMSE/MOCA score available, or where recorded in medical records.

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20 247 (4) These will be excluded: Patients who have a severe visual or auditory impairment, serious
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22 248 medical conditions in major organs (heart, lung or kidney), illnesses affecting mobility or are
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24 249 unable to accept assessments or interventions that are required in this study for any reasons.

25 250 **Types of exercise intervention**

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27 251 This systematic review will include all studies involving any type of exercise. Exercise
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29 252 intervention is defined as a type of physical activity that is planned, structured and repeated
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31 253 over a period of time.³⁵ The eligible exercise can be categorized into resistance training,
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33 254 aerobic exercise, combined exercise and other types of training. In addition, all organizational
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35 255 forms of intervention (individual, group, or mixed) are eligible for inclusion. Besides,
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37 256 supportive strategies (face to face, telephone, email) will be eligible for inclusion. There will
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39 257 be no limitations about the professional background of the person sustaining the exercise
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41 258 interventions, additionally unsustained (self-guided/self-administered) interventions will also
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43 259 be eligible for inclusion.

44 260 **Type of setting**

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46 261 Studies in any setting where exercise intervention is conducted including healthcare
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48 262 institutions, community, home or in any geographical setting globally will be considered for
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50 263 inclusion.

51 264 **Types of outcome measures**

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53 265 Outcomes of studies that report barriers and enablers influencing uptake/maintenance of
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55 266 exercise in older adults with MCI/dementia will be included.

56 267 **Types of studies**

268 The searches are not limited to specific study design. Hence, all study designs using
 269 qualitative or quantitative methodologies will be included in the review. The papers will be
 270 categorized by study design using the following categories: randomized-controlled trial,
 271 quasi-controlled trial, cohort study, cross-sectional study and qualitative study.

272 **The language of studies**

273 Searches will be no limitation in language publications.

274 **Publication year**

275 Studies published between January 1990 and February 2020.

276 **Information sources**

277 The following electronic databases: PubMed, Embase, The Cochrane Library, Web of
 278 Science, China National Knowledge Infrastructure (CNKI), and the Wan Fang Database will
 279 be searched from January 1990 to February 2020 about Human studies. In order to improve
 280 the completeness of the literature, grey literature sources will be considered. We will further
 281 check the reference list of the included studies and relevant reviews.

282 **Search strategy**

283 Based on key terms from previous literature reviews and Medical Subject Headings,
 284 our search will use both the medical subject headings and text word and will combine
 285 concepts for the influencing factors of adherence. Our search strategy will consist of three
 286 parameters: disease (MCI/dementia), intervention (exercise) and outcome (adherence). The
 287 search strategy we will use for the retrieval of reports of trials from PubMed is summarized in
 288 Table 1. The search strategy will be modified as necessary for other databases.

Table 1 The search strategy of PubMed

Number	Search items
1	Dementia OR Cognitive Dysfunction OR Mild Cognitive Impairment* OR MCI OR VCI OR AAMI OR SMC OR ACMI OR ARCD OR CIND OR (nMCI or aMCI or mMCI or MCIa) OR MCD OR AACD OR MNCD OR Mild Neurocognitive Disorder* OR cogn* OR Cognitive impairment OR Alzheimer OR AD OR Alzheimer's disease
2	Ageing OR aging OR Elderly OR "Aged,80 and over" OR "Old* age*" OR "middle age*" OR "old* adults" OR senior* OR senior citizens OR old people OR old person

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4 3 Exercise OR Physical activit* OR Treadmill training OR Balance OR Strength OR
5 Endurance OR Attention training sport* OR jogging OR physical therapy OR
6 physiotherapy OR exercise* OR fitness OR rehabilitation OR flexibility OR aerobic
7 training OR resistance training OR motor activit* OR leisure activit* OR strength OR
8 balance OR aerobic* OR physical* OR training OR bicycling OR cycling OR swim* OR
9 gym* OR walk* OR danc* OR yoga OR joga OR tai chi OR tai ji OR taichi OR
10 Taijiquan OR tai-chi OR pilates OR movement OR recovery of function OR inactivit*
11 OR sedentary OR physical inactivit* OR occupational therapy OR physical stimulation
12 OR physical education OR physical medicine OR resistance OR mind-body OR Mind
13 Body OR mind body OR mind-body training
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23 4 barrier* OR enabler* OR motivators OR facilitators OR implementation OR adherence
24 OR compliance OR support OR self-efficacy OR self efficacy OR self-efficiency OR
25 motivation OR experience* OR perspective* OR factor* OR attendance OR
26 predictor*OR preference*
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31 5 1 and 2 and 3 and 4
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290 **The selection process of studies**

291 The study selection process will be reported according to the PRISMA flowchart.³⁶ First,
292 removing duplicates using the reference manager software Endnote X7. Then titles and
293 abstracts of articles will be screened. Selected full-text articles will be assessed for eligibility.
294 The process will be carried by two independent researchers (HY and YX C), disagreement
295 will be solved by discussion. A third researcher (CX G) will be invited in case of persistent
296 contradiction. In the final, two other authors (HQ C and JW) will assess potentially eligible
297 full-text studies to make sure if they meet the criteria set for inclusion.

298 **Risk of bias (quality) assessment and meta-bias**

299 Two independent reviewers rigorously will assess the quality of each paper. The
300 Newcastle-Ottawa Scale (NOS) will be used to assess the quality of cohort articles.³⁷
301 Cross-sectional studies will be examined using the Agency for Healthcare Research and
302 Quality (AHRQ).³⁸ Randomized controlled trials will be assessed according to PEDpro.³⁹ The

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4 303 Joanna Briggs Institute (JBI) critical appraisal checklist will be used to assess the quality of
5
6 304 quasi-randomized controlled trials.⁴⁰ Qualitative research will adopt the tool that JBI made
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8 305 critical appraisal tools for qualitative research in 2016.⁴¹

9
10 306 **Data extraction and synthesis**

11 307 Because of this expected significant heterogeneity in the included studies in terms of methods,
12
13 308 participants, interventions and study types may limit our ability to conduct a meta-analysis. It
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15 309 will be the main limitation of the study. A narrative synthesis is planned as informed by the
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17 310 published guidelines.⁴² ‘Narrative synthesis’ refers to an approach to the systematic review
18
19 311 and synthesis of findings from multiple studies that rely primarily on the use of words and
20
21 312 text to summarize and explain the findings of the synthesis.⁴² Narrative methods have long
22
23 313 been recognized as useful for investigating heterogeneity across primary studies and
24
25 314 developing an understanding of which aspects of an intervention may be responsible for its
26
27 315 success.⁴³

28
29 316 Therefore, this review will adopt a narrative synthesis to synthesize all related qualitative
30
31 317 and quantitative literature. After the full-text screening, all included studies will be imported
32
33 318 into NVivo.12 for data extraction using a line by line approach and coding of the data. The
34
35 319 extracted information will include study characteristics and modifiable enablers and barriers
36
37 320 of exercise adherence in older adults with MCI/dementia. Study characteristics
38
39 321 are as follows:

40
41 322 **(1) Bibliographic information:** the journal name, title, first author’s name, publication year,
42
43 323 language of the study, country of the corresponding author.

44
45 324 **(2) Study design:** the specific type of study, exercise intervention technique, duration,
46
47 325 outcomes measured, instruments used to measure them, sample size and quality of the study.

48
49 326 **(3) Participants data:** type of disease, disease screening tools/diagnostic tools, setting,
50
51 327 inclusion and exclusion criteria, sociodemographic characteristics (e.g. age, ethnicity,
52
53 328 country).

54
55 329 **(4) Outcomes:** definition of adherence and rate of adherence. Adherence was defined as the
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57 330 percentage of attended sessions during the programs as registered by the instructors in
58
59 331 most studies.¹⁴ Generally considering that participants meet the requirement of adherence
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4 332 when they complete more than seventy percent sessions of the whole program.⁴⁴⁻⁴⁶ Yet, there
5
6 333 is not an accepted standard for exercise adherence. Grove and Spier defined adherence as the
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8 334 percentage of older adults who attended ninety percent of sessions.⁴⁷ Keogh et al. described
9
10 335 adherence as having attended one session a week over the previous 3 months.⁴⁸ It
11
12 336 is acknowledged that there is a large difference in the definition of exercise adherence. We
13
14 337 will describe the definition of exercise adherence in selected studies. It may be helpful for us
15
16 338 to analyze the differences in research results and make the study more transparent.

17 339 The TDF is defined a priori framework to reflect all coding of data. Coding of data will
18
19 340 include such as authors' descriptions of the results and all relevant quotes from participants
20
21 341 provided in the results section (or results tables) of included studies. We will map the
22
23 342 modifiable barriers and enablers of exercise adherence into following 14 domains with 14
24
25 343 coding information of the TDF: (1) Knowledge, (2) Skills, (3) Social influences, (4) Memory,
26
27 344 attention and decision processes, (5) Behavioural regulation, (6) Professional/Social role and
28
29 345 identity, (7) Beliefs about capabilities, (8) Belief about consequences, (9) Optimism, (10)
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31 346 Intentions, (11) Goals, (12) Emotion, (13) Environmental context and resources and (14)
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33 347 Reinforcement. (15) Any barriers/enablers that do not fit within the existing domains of the
34
35 348 TDF will be organized into the 'Others' domain.⁴⁹

36
37 349 In the NVivo.12, we will build three themes from the perspective of the patients,
38
39 350 caregivers and health care professionals to conform to the aim of our study. Each theme will
40
41 351 be divided into two subthemes (modified barriers and enablers). For each of these subthemes,
42
43 352 we will create 15 domains. For example, if we extracted the following text in a study
44
45 353 'Participant A reported that the intensity of the program was too high that affected his/her
46
47 354 maintenance'. We would code it into TDF domain 'Goals'. Then we will compare our coding
48
49 355 to generate consensus about identified barriers and enablers in the literature. It will be
50
51 356 possible that the same sentence will be assigned more than one code. This process will be
52
53 357 undertaken and will be discussed by two authors (XT Z, HQ C). Any disagreement between
54
55 358 the two researchers will be resolved through further discussion and adjudication by a third
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57 359 reviewer (J W). When there is a disagreement in different study facing the same factor
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59 360 affecting exercise adherence, we will evaluate the state of the literature (such as literature
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4 361 quality, types of research, sample size and so on) and explain potential differences in results
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6 362 across studies. Poor methodological quality will not be included in the review that will affect
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8 363 the trustworthiness of the synthesis. In the meantime, we will take some measures to
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10 364 minimize bias, for example, that studies judged to be of equal technical quality are given
11
12 365 equal weight or if not providing a sound justification for not doing so.⁴² We will also try our
13
14 366 best to explore the influence of heterogeneity in this stage of the synthesis process.

15 367 **DISCUSSION**

16
17 368 Understanding modifiable barriers and enablers to exercise for older adults with
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19 369 MCI/dementia is a complex process that needs to be fully explored if we are to capitalise on
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21 370 the value exercise can offer. To date, existing research on this topic has not been synthesized.
22
23 371 This review will synthesize and report qualitative and quantitative data about exercise
24
25 372 adherence from the perspective of patients, caregivers and health care professionals.

26
27 373 This study will have several strengths and implications. First, the results will contribute to
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29 374 understanding common influencing factors to focus on how to modify barriers best and
30
31 375 enhance enablers to increase the use and appeal for the exercise intervention. Second, it will
32
33 376 facilitate effective access to care and treatment to help older adults with MCI/dementia have a
34
35 377 broader adoption to exercise intervention. Third, it will have substantial implications for
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37 378 researchers, clinicians, and policymakers about how to provide better special care for older
38
39 379 adults with MCI/dementia. We anticipate that this work will also be highly correlated to the
40
41 380 public who want to engage with the exercise program. Last but not the least, this systematic
42
43 381 review will be the first try that map modifiable barriers and enablers of exercise for older
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45 382 adults with MCI/dementia to the domains of the TDF. In theory, TDF is a comprehensive
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47 383 framework that synthesizes many behaviour change theories, which lower the risks of
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49 384 missing relevant theoretical constructs or including irrelevant ones. Hence, it can be used for
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51 385 summarizing the related factors of exercise adherence reported in the literature from all
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53 386 angles. From a practical point of view, the usefulness of TDF has been confirmed in various
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55 387 medical practices gradually. In view of the effectiveness of TDF, it therefore offers an
56
57 388 appropriate framework to synthesize extensive barriers and enablers reported in single studies.
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59 389 The results will also provide a more in-depth insight into the influences on evidence-based
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4 390 behaviour change. Findings based on the framework can be used to inform the development
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6 391 of effective adherence interventions to assist practitioners in choosing the most suitable
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8 392 evidence-based exercise programs in clinical settings accordingly.

9 393 **Amendments**

11 394 If we need to amend this protocol, the date of each amendment will be accompanied by a
12
13 395 description of the change and the rationale.

15 396 **Patient and public involvement**

17 397 Patients and the public were not involved at this stage of the project.

19 398 **Ethical issues**

21 399 The systematic review is a retrospective study, using publicly available data. As no primary
22
23 400 data collection will be undertaken and does not require a formal ethical assessment and no
24
25 401 informed consent are needed.

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29 403 **Conflict of interest**

31 404 All authors declare that we have no conflicts of interest.

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42
43 410 writing of theprotocol.

45 411 **Contributors**

46 412 All authors contributed to the development of the study design and search strategy. XT Z and
47
48 413 LN W designed the study and wrote the protocol. XT Z and H Y wrote the search strategy. H
49
50 414 Y, YX C and CX G screened the literature. WJ and HQ C checked the selected article. All
51
52 415 authors provided feedback and approved the final protocol.

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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

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In your methods section, say that you used the PRISMA-Reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

	Reporting Item	Page Number
Title		
Identification	#1a Identify the report as a protocol of a systematic review	1
Update	#1b If the protocol is for an update of a previous systematic review, identify as such	n/a not an update

1 **Registration**

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4 [#2](#) If registered, provide the name of the registry (such as 4

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6 PROSPERO) and registration number

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10 **Authors**

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13 **Contact** [#3a](#) Provide name, institutional affiliation, e-mail address of 1-2

14

15 all protocol authors; provide physical mailing address of

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17 corresponding author

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20 **Contribution** [#3b](#) Describe contributions of protocol authors and identify 15

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22 the guarantor of the review

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26 **Amendments**

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29 [#4](#) If the protocol represents an amendment of a 15

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31 previously completed or published protocol, identify as

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33 such and list changes; otherwise, state plan for

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35 documenting important protocol amendments

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39 **Support**

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42 **Sources** [#5a](#) Indicate sources of financial or other support for the n/a not included

43

44 review

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47 **Sponsor** [#5b](#) Provide name for the review funder and / or sponsor 15

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50 **Role of sponsor** [#5c](#) Describe roles of funder(s), sponsor(s), and / or 15

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52 or funder institution(s), if any, in developing the protocol

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56 **Introduction**

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1	Rationale	#6	Describe the rationale for the review in the context of	4-8
2			what is already known	
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6	Objectives	#7	Provide an explicit statement of the question(s) the	8-9
7			review will address with reference to participants,	
8			interventions, comparators, and outcomes (PICO)	
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14	Methods			
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17	Eligibility criteria	#8	Specify the study characteristics (such as PICO, study	8-10
18			design, setting, time frame) and report characteristics	
19			(such as years considered, language, publication	
20			status) to be used as criteria for eligibility for the review	
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27	Information	#9	Describe all intended information sources (such as	10
28			electronic databases, contact with study authors, trial	
29	sources		registers or other grey literature sources) with planned	
30			dates of coverage	
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37	Search strategy	#10	Present draft of search strategy to be used for at least	10-11
38			one electronic database, including planned limits, such	
39			that it could be repeated	
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45	Study records -	#11a	Describe the mechanism(s) that will be used to manage	12-14
46	data		records and data throughout the review	
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48				
49	management			
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52	Study records -	#11b	State the process that will be used for selecting studies	11
53	selection process		(such as two independent reviewers) through each	
54			phase of the review (that is, screening, eligibility and	
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inclusion in meta-analysis)

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4	Study records -	#11c	Describe planned method of extracting data from
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6	data collection		reports (such as piloting forms, done independently, in
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8	process		duplicate), any processes for obtaining and confirming
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10			data from investigators
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13	Data items	#12	List and define all variables for which data will be
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15			sought (such as PICO items, funding sources), any pre-
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17			planned data assumptions and simplifications
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21	Outcomes and	#13	List and define all outcomes for which data will be
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23	prioritization		sought, including prioritization of main and additional
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25			outcomes, with rationale
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29	Risk of bias in	#14	Describe anticipated methods for assessing risk of bias
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31	individual studies		of individual studies, including whether this will be done
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33			at the outcome or study level, or both; state how this
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35			information will be used in data synthesis
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39	Data synthesis	#15a	Describe criteria under which study data will be
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41			quantitatively synthesised
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49	Data synthesis	#15b	If data are appropriate for quantitative synthesis,
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51			describe planned summary measures, methods of
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53			handling data and methods of combining data from
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55			studies, including any planned exploration of
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57			consistency (such as I ² , Kendall's τ)
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1	Data synthesis	#15c	Describe any proposed additional analyses (such as	n/a	no meta-
2			sensitivity or subgroup analyses, meta-regression)		analysis or other
3					statistical
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11	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the		12
12			type of summary planned		
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16	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es)	n/a	no meta-
17			(such as publication bias across studies, selective		analysis or other
18			reporting within studies)		statistical
19					analysis
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26	Confidence in	#17	Describe how the strength of the body of evidence will		n/a
27			be assessed (such as GRADE)		
28	cumulative				
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Notes:

- 37 • 1b: n/a not an update
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- 40 • 5a: n/a not included
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- 42
- 43 • 15a: n/a no meta-analysis or other statistical analysis
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- 46 • 15b: n/a no meta-analysis or other statistical analysis
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- 49 • 15c: n/a no meta-analysis or other statistical analysis
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- 51
- 52 • 16: n/a no meta-analysis or other statistical analysis The PRISMA-P checklist is distributed under
- 53 the terms of the Creative Commons Attribution License CC-BY 4.0. This checklist was completed
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BMJ Open

Modifiable facilitators and barriers to exercise adherence in older adults with MCI/dementia using the Theoretical Domains Framework: a systematic review protocol

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Primary Subject Heading:	Mental health
Secondary Subject Heading:	Mental health, Geriatric medicine, Nursing
Keywords:	mild cognitive impairment, Dementia < NEUROLOGY, exercise, adherence, factors

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4 1 **Modifiable facilitators and barriers to exercise adherence in older adults with**
5 2 **MCI/dementia using the Theoretical Domains Framework: a systematic review protocol**
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11 4 Xueting Zhen¹, Lina Wang^{1&#}, Hang Yan², Hong Tao³, Yaxiu Cai⁴, Jie Wang⁵, Haiqin Chen⁶,
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29 56 **Key words:** mild cognitive impairment; dementia; exercise; adherence; factors;
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57 66 **Modifiable facilitators and barriers to exercise adherence in older adults**
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4 67 **with MCI/dementia using the Theoretical Domains Framework: a**
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6 68 **systematic review protocol**
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12 70 **ABSTRACT**

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15 71 **Introduction** Exercise has multiple benefits on maintaining or improving cognitive function
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17 72 for people with mild cognitive impairment (MCI)/dementia. However, many older adults with
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19 73 MCI/dementia are not sufficiently active to achieve these benefits. Allowing for the current
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21 74 studies on exercise adherence in older adults with MCI/dementia still have some deficiencies.
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23 75 This paper aims : (1) to identify the modifiable facilitators and barriers to exercise adherence
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25 76 for older adults with MCI/dementia in terms of the perspectives of patients, caregivers and
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27 77 health care professionals; (2) to organise the identified factors of exercise adherence base on
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29 78 the Theoretical Domains Framework (TDF) among included studies.

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31 79 **Methods and analysis** A systematic computerised literature search will be performed in the
32
33 80 following online databases: PubMed, Embase, Cochrane Library, Web of Science, China
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35 81 National Knowledge Infrastructure (CNKI), Wan Fang Database, which published between
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37 82 January 1990 and June 2020. We will identify peer-reviewed publications which examined
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39 83 facilitators and barriers to exercise adherence. Searches will no limitation in language
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41 84 publications using search terms related to exercise interventions, adherence and
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43 85 MCI/dementia. Two independent reviewers will screen titles, abstracts and full-text articles
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45 86 according to the predetermined inclusion and exclusion criteria. We will use the statistical
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47 87 software Nvivo.12 to manage the information. Basing on the Theoretical Domains
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49 88 Framework (TDF), we will map identified modifiable facilitators and barriers of literature to
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51 89 the domains of TDF.

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54 90 **Ethics and dissemination** This review will summarise modifiable facilitators and barriers to
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56 91 exercise adherence for older adults with MCI/dementia for the first time. Ethical approval is
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58 92 not required as no primary data are collected. We are going to disseminate our findings to the

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4 93 scientific and medical community in peer-reviewed journals. The review findings will
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6 94 facilitate adequate and accurate access to care and treatment to help older adults with
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8 95 MCI/dementia have a broader adoption to exercise.

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10 96 **PROSPERO registration number** CRD42019117725
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15 98 **Strengths and limitations of this study**

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18 99 1. To the best of our knowledge, previous work didn't systematically map and categorise
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20 100 modifiable facilitators and barriers to exercise adherence about older adults with
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22 101 MCI/dementia, referring to the Theoretical Domains Framework.

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25 102 2. Our systematic review will be the first attempt to summarise the currently available
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27 103 evidence on the insights of patients, caregivers and health care professionals.

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30 104 3. We will perform an all-round search of published and grey literature with no restrictions on
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33 105 language and geographical location.

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36 106 4. The main limitation of the study is that no meta-analysis or other statistical analysis will be
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38 107 performed in this review.

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42 109 **BACKGROUND**

43 110 **Description of the MCI/dementia condition**

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46 111 Mild Cognitive Impairment (MCI) is the intermediate phase between normal cognitive
47
48 112 function and dementia, characterised by a delay in cognitive decline that is larger than
49
50 113 expected considering a person's age and education, though without marked interference in
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52 114 daily-life activities.¹ The published prevalence of people with MCI is approximately 10% to
53
54 115 20% worldwide depending on the sample and the follow-up duration of studies.² People with
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4 116 MCI have a heightened risk of further cognitive decline and progression to dementia. After
5
6 117 an initial diagnosis of MCI, the incidence of dementia within 1, 5, and 9.5 years was 10-15,
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8 118 60.5 and 100%, respectively.³ Dementia is characterised by progressive and severe cognitive
9
10 119 decline, motor deficits with or without behavioural problems causing a decrease in activities
11
12 120 of daily living (ADL).⁴ As life expectancy is getting longer worldwide, the number of people
13
14 121 affected by MCI and dementia is steadily growing.⁵ According to estimates from the World
15
16 122 Alzheimer Report, the number of people with dementia will dramatically increase in the
17
18 123 coming decades, from 47 million in 2015 to 131.5 million by 2050.⁶ These rapidly growing
19
20 124 numbers will have a tremendous social impact, placing a high economic burden on the health
21
22 125 care system.⁶⁻⁷

23
24 126 To date, there are no definite or disease-modifying therapeutic options for dementia and
25
26 127 MCI. For the pharmacological interventions of dementia and MCI, these drugs may initially
27
28 128 improve cognition and slow down the clinical progression of MCI/dementia. They are not
29
30 129 capable of stopping the underlying pathological process of disease including amyloid
31
32 130 accumulation, tau protein aggregation, synaptic loss and neuronal death.⁸⁻⁹ Currently, many
33
34 131 non-pharmacological treatments have reported benefits on cognitive function for older adults
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36 132 with MCI/dementia in multiple research studies.¹⁰⁻¹¹ As one of the significant
37
38 133 recommendations for non-pharmaceutical interventions, exercise has been consistently
39
40 134 proved to be associated with a reduced risk of developing MCI/dementia. Exercise (aerobic
41
42 135 training, resistance training and mind-body practice, etc.) is a promising strategy for
43
44 136 preventing or delaying cognitive decline, and its salutary effects on cognitive function have
45
46 137 been demonstrated in animal models and a growing number of clinical studies of older adults
47
48 138 with MCI/dementia.¹²⁻¹⁴

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50 139 Despite these positive findings, there remain concerns that older adults with
51
52 140 MCI/dementia are physically inactive, and their adherence to exercise is poor.¹⁵⁻¹⁶ One study
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54 141 with older adults with MCI showed that only 25% of participants continued to apply for the
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56 142 exercise programs after the end of the 12-month randomised controlled trial (RCT).¹⁶ Only
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58 143 19% of the individual with dementia completed more than two-thirds possible exercise

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4 144 sessions in the other one yearlong trial study, 52% of participants just finished less than
5
6 145 one-third of possible practices and the mean adherence rate was $33.2\pm 25.5\%$ in the whole
7
8 146 sessions.¹⁵ Thus the adherence to exercise interventions was still not optimistic for older
9
10 147 adults with MCI/dementia, and we would need to pay more attention to relevant researches of
11
12 148 exercise adherence.

149 **The significance of doing this review**

150 The positive effects of all exercise interventions depend highly on exercise adherence.¹⁷

151 Lowery D et al. also concluded that it is essential to identify factors influencing the
152 participation among older adults with dementia in the community since only 30.7%
153 participants have achieved the prescribed frequency of the exercise in their research.¹⁸ To
154 increase exercise adherence levels of older adults with MCI/dementia, there is a need to
155 understand the factors better that affect exercise adherence in such populations. Specifically,
156 identifying the facilitators and barriers to exercise will contribute to the implementation of
157 the exercise intervention according to the initial protocol, which will promote
158 the rehabilitation for older adults with dementia. Some previous studies have established the
159 factors associated with exercise participation in community-dwelling adults with dementia,
160 including increased energy intake, resting metabolic rate, fat-free mass, gait speed, taking \geq
161 four medications, dizziness, lower ADL function, a history of falls, delirium and so on.¹⁹⁻²⁰

162 However, the current studies on exercise adherence in older adults with MCI/dementia
163 still have the following deficiencies:

164 ***(1) The absence of research on discussing on exercise adherence in terms of different*** 165 ***insights***

166 The insights of patients, caregivers and health care professionals often differ regarding the
167 facilitators and barriers to exercise adherence due to differing priorities and knowledge of the
168 situation.²¹⁻²⁸ For patients, the complicity of symptoms can make it more difficult for older
169 adults with MCI/dementia to participate in exercise programs. Older adults with

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4 170 MCI/dementia can usually express their views and preferences about what is important to
5
6 171 them when exercising, and it is morally and ethically necessary to consider those views.²¹⁻²²
7
8 172 In comparison to caring for older adults with normal cognitive function, the caregivers taking
9
10 173 care of older adults with MCI/dementia face a substantially higher burden due to changes that
11
12 174 are typically associated with dementia.²³⁻²⁴ Relatively little is known on how caregivers of
13
14 175 older adults with MCI/dementia manage their support arrangements, which strategies they
15
16 176 follow and which ways are perceived as helpful or obstructive in exercise.²⁴⁻²⁵ Therefore,
17
18 177 opinions from caregivers should be taken into account. Furthermore, previous studies also
19
20 178 highlighted the importance of support from health care professionals to encourage older
21
22 179 adults with MCI/dementia to take part in the exercise.²⁶⁻²⁷ The research has shown that
23
24 180 participants' adherence to exercise is improved when the instructions they receive are specific
25
26 181 and understandable from health care professionals.²⁸ In the meantime, many health care
27
28 182 professionals were also concerned about participants' ability to access exercise programs.^{16,27}
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30 183 Caregivers may build bridges in following the instructions from health care professionals and
31
32 184 monitoring exercise implementation better.²³⁻²⁵ Teamwork and collaboration among patients,
33
34 185 caregivers and health care professionals become paramount to improve the exercise
35
36 186 adherence for older adults with MCI/dementia. Currently, the facilitators and barriers to
37
38 187 exercise adherence among older adults with MCI/dementia in insights of different
39
40 188 perspectives have not been studied.

41
42 189 ***(2) The lack of the utility of a theoretical framework to organise the potential facilitators***
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44 190 ***and barriers to exercise adherence***

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46 191 Previous studies on facilitators and barriers to exercise adherence for older adults with
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48 192 MCI/dementia lacked the support or elaboration of behavioural theory framework.
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50 193 Behavioural theory can provide potential determinants and a corresponding structure for
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52 194 thinking logically about these determinants and their relationships.²⁹ Applying a behavioural
53
54 195 theoretical framework for assessing facilitators and barriers can effectively help develop
55
56 196 tailored informed strategies to support the effective implementation of evidence-based
57
58 197 practices.³⁰ In this study, we will rely on Theoretical Domains Framework (TDF) to classify

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4 198 facilitators and barriers to exercise adherence for older adults with MCI/dementia. The TDF
5
6 199 is a comprehensive framework that synthesises several behaviour change theories. It was
7
8 200 developed with 12 domains and 128 constructs initially, and its validity was reevaluated by
9
10 201 Michie et al with a refined version with 14 domains and 84 constructs.³¹⁻³² This framework
11
12 202 offers an appropriate structure for supporting an evidence synthesis of facilitators and barriers
13
14 203 as it will help these factors to be linked to evidence-based behaviour change techniques. This
15
16 204 theory has been used widely and successfully to assess facilitators and barriers, and provides
17
18 205 a theory-driven guide for the further effective interventions.³³⁻³⁵ Therefore, the TDF will
19
20 206 contribute to overall understanding the facilitators and barriers to exercise adherence for older
21
22 207 adults with MCI/dementia.

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24 208 ***(3)The lack of systematic research on the modifiable factors that impact exercise***
25
26 209 ***adherence for older adults with MCI/dementia***

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28
29 210 It is recognised that the facilitators and barriers to targeted exercise amongst older adults with
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31 211 MCI/dementia are multifactorial.¹⁶⁻²⁰ Furthermore, these factors are partly unmodifiable or
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33 212 unavoidable that is difficult for us to change (e.g. family history, sex and age). Identification
34
35 213 of the potentially modifiable factors, which may improve or deteriorate exercise adherence is
36
37 214 a critical approach to design interventions. This information will serve as a reminder that
38
39 215 guides medical staff in refining target population and intervention methods theoretically, and
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41 216 then contributing to developing the adherence oriented exercise programs in practice.
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43 217 Therefore, we first attempt to identify primary research findings of modifiable facilitators and
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45 218 barriers that may help to design exercise strategies to improve the effectiveness of exercise
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47 219 interventions further.

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49 220 As summarised in the above, according to a broad-based theoretical framework for
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51 221 behaviour change, an overall understanding of the modifiable facilitators and barriers to
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53 222 exercise intervention in insights of the perspectives of patients, caregivers and health care
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55 223 professionals is needed. Thus we aim to conduct a systematic review to collect and
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57 224 summarise the available evidence on modifiable facilitators and barriers to exercise

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4 225 adherence for older adults with MCI/dementia. Then this study will further categorise these
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6 226 modifiable factors into the domains presented in the TDF. These findings will provide
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8 227 medical staff recommendation with the individual-tailored exercise prescriptions and
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10 228 contribute to developing the strategies of long-term exercise adherence for older adults with
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12 229 MCI/dementia.

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17 231 **METHODS/DESIGN**

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20 232 This protocol is written following the recommendation of the Preferred Reporting Items for
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22 233 Systematic Review and Meta-analysis Protocols (PRISMA-P).³⁶ We plan to complete the
23
24 234 systematic review with an expected completion date of March 31, 2021. This review has been
25
26 235 registered with the international database of prospectively registered systematic reviews in
27
28 236 health and social care (PROSPERO; registration number CRD42019117725).

30 237 **Eligibility criteria**

33 238 **Types of participants**

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36 239 Eligible studies will include any type of MCI/dementia. No limitations will be placed on the
37
38 240 severity of MCI/dementia, length of time since diagnosis. No restrictions will be placed on
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40 241 the severity of depression, anxiety, psychological distress or mental health-related quality of
41
42 242 life. These individuals will be included as follows:

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45 243 (1) The people aged 65 years or older.

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47 244 (2) For dementia: Including studies involving people diagnosed with any type of dementia,
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49 245 according to the criteria in the Diagnostic and Statistical Manual of Mental Disorders, Third
50
51 246 Edition (DSM-3), Fourth Edition (DSM-4), Text Revision (DSMIV-TR), Fifth Edition
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53 247 (DSM-5), International Classification of Diseases, Tenth Revision (ICD-10), Mini-Mental
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55 248 State Examination (MMSE)/Montreal Cognitive Assessment (MOCA) score available, other
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57 249 alternative validated diagnostic criteria or recorded in medical records.

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4 250 (3) For MCI: Including studies involving people diagnosed with any type of MCI, according
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6 251 to the criteria in the DSM-5 criteria, Petersen's criteria, an alternative validated diagnostic
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8 252 criteria, MMSE/MOCA score available, or where recorded in medical records.
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11 253 (4) These will be excluded: Patients who have a severe visual or auditory impairment, serious
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13 254 medical conditions in major organs (heart, lung or kidney), illnesses affecting mobility or are
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15 255 unable to accept assessments or interventions that are required in this study for any reasons.
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17 256 **Types of exercise intervention**

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20 257 This systematic review will include all studies involving any one of exercise treatment or
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22 258 intervention. Exercise intervention is defined as a type of physical activity that is planned,
23
24 259 structured and repeated over a while.³⁷ The eligible exercise can be categorised into
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26 260 resistance training, aerobic exercise, combined exercise and other types of training. Also, all
27
28 261 organisational forms of exercise intervention (individual, group, or mixed) are eligible for
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30 262 inclusion. Besides, supportive strategies (face to face, telephone, email) will be eligible for
31
32 263 inclusion. There will be no limitations about the professional background of the person
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34 264 sustaining the exercise interventions, additionally unsustained (self-guided/self-administered)
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36 265 interventions will also be eligible for inclusion.
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38 266 **Type of setting**

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41 267 Studies in any setting where exercise intervention is conducted, including health care
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43 268 institutions, community, home or in any geographical setting globally will be considered for
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45 269 inclusion.
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47 270 **Types of outcome measures**

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50 271 Outcomes of studies that report facilitators and barriers influencing uptake/maintenance of
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52 272 exercise for older adults with MCI/dementia will be included.
53

54 55 273 **Types of studies**

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58 274 The searches are not limited to specific study design. Hence, all study designs using
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275 qualitative or quantitative methodologies will be included in the review. The papers will be
 276 categorised by study design using the following categories: randomised-controlled trial,
 277 quasi-controlled trial, cohort study, cross-sectional study and qualitative study.

278 **The language of studies**

279 Searches will be no limitation in language publications.

280 **Publication year**

281 Studies published between January 1990 and June 2020.

282 **Information sources**

283 The following electronic databases: PubMed, Embase, Cochrane Library, Web of Science,
 284 China National Knowledge Infrastructure (CNKI), and Wan Fang Database will be searched
 285 from January 1990 to June 2020 about Human studies. In order to improve the completeness
 286 of the literature, grey literature sources will be considered. We will further check the
 287 reference list of the included studies and relevant reviews.

288 **Search strategy**

289 Based on key terms from previous literature reviews and Medical Subject Headings,
 290 our search will use both the medical subject headings and text word and will combine
 291 concepts for the influencing factors of adherence. Our search strategy will consist of three
 292 parameters: disease (MCI/dementia), intervention (exercise) and outcome (adherence). The
 293 search strategy we will use for the retrieval of reports of trials from PubMed is summarised in
 294 Table 1. The search strategy will be modified as necessary for other databases.

Table 1 The search strategy of PubMed

Number	Search items
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- 1
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3
4 1 Dementia OR Cognitive Dysfunction OR Mild Cognitive Impairment* OR MCI OR VCI
5 OR AAMI OR SMC OR ACMI OR ARCD OR CIND OR (nMCI or aMCI or mMCI or
6 MCIa) OR MCD OR AACD OR MNCD OR Mild Neurocognitive Disorder* OR cogn*
7 OR Cognitive impairment OR Alzheimer OR AD OR Alzheimer's disease
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14
15 2 Ageing OR aging OR Elderly OR "Aged,80 and over" OR "Old* age*" OR "middle
16 age*" OR "old* adults" OR senior* OR senior citizens OR old people OR old person
17
18
19 3 Exercise OR Physical activit* OR Treadmill training OR Balance OR Strength OR
20 Endurance OR Attention training sport* OR jogging OR physical therapy OR
21 physiotherapy OR exercise* OR fitness OR rehabilitation OR flexibility OR aerobic
22 training OR resistance training OR motor activit* OR leisure activit* OR strength OR
23 balance OR aerobic* OR physical* OR training OR bicycling OR cycling OR swim* OR
24 gym* OR walk* OR danc* OR yoga OR joga OR tai chi OR tai ji OR taichi OR
25 Taijiquan OR tai-chi OR pilates OR movement OR recovery of function OR inactivit*
26 OR sedentary OR physical inactivit* OR occupational therapy OR physical stimulation
27 OR physical education OR physical medicine OR resistance OR mind-body OR Mind
28 Body OR mind body OR mind-body training
29
30
31
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40 4 barrier* OR enabler* OR motivators OR facilitators OR implementation OR adherence
41 OR compliance OR support OR self-efficacy OR self efficacy OR self-efficiency OR
42 motivation OR experience* OR perspective* OR factor* OR attendance OR predictor*
43 OR preference*
44
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49 5 1 and 2 and 3 and 4
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296 **The selection process of studies**

297 The study selection process will be reported according to the PRISMA flowchart.³⁸ First,

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4 298 removing duplicates using the reference manager software Endnote X7. Then titles and
5
6 299 abstracts of articles will be screened. Selected full-text articles will be assessed for eligibility.
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8 300 The process will be carried by two independent researchers (HY and YX C), disagreement
9
10 301 will be solved by discussion. A third researcher (CX G) will be invited in case of persistent
11
12 302 contradiction. In the final, two other researchers (HQ C and JW) will assess potentially
13
14 303 eligible full-text studies to make sure if they meet the criteria set for inclusion.

304 **Risk of bias (quality) assessment and meta-bias**

305 Two independent reviewers rigorously will assess the quality of each paper. This study will
306 use the Newcastle-Ottawa Scale (NOS)³⁹ for evaluating the quality of the cohort studies, use
307 the Agency for Health care Research and Quality (AHRQ)⁴⁰ for assessing the quality of the
308 cross-sectional studies and apply the Physiotherapy Evidence Database (PEDro)⁴¹ scale for
309 estimating the quality of the randomised controlled trials. The Joanna Briggs Institute (JBI)
310 critical appraisal checklist will be used to determine the quality of quasi-randomised
311 controlled trials.⁴² Qualitative research will adopt the tool that JBI made essential tools of
312 appraisal for qualitative research in 2016.⁴³

313 **Data extraction and synthesis**

314 Because of this expected significant heterogeneity in the included studies in terms of methods,
315 participants, interventions, and study types may limit our ability to conduct a meta-analysis. It
316 will be the main limitation of the study. A narrative synthesis will be planned as informed by
317 the published guidelines.⁴⁴ 'Narrative synthesis' refers to an approach to the systematic
318 review and synthesis of findings from multiple studies that rely primarily on the use of words
319 and text to summarise and explain the results of the integration.⁴⁴ Narrative methods have
320 long been recognized as useful for investigating heterogeneity across primary studies and
321 developing an understanding of which aspects of an intervention may be responsible for its
322 success.⁴⁵

323 Therefore, this review will adopt a narrative synthesis to synthesise all related qualitative

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4 324 and quantitative studies. After the full-text screening, all included studies will be imported
5
6 325 into NVivo.12 for data extraction using a line by line approach and coding of the data. The
7
8 326 extracted information will consist of study characteristics and modifiable facilitators and
9
10 327 barriers to exercise adherence in older adults with MCI/dementia. Study characteristics
11
12 328 are as follows:

13
14 329 **(1) Bibliographic information:** the journal name, title, first author's name, publication year,
15
16 330 language of the study, country of the corresponding author.

17
18
19 331 **(2) Study design:** the specific type of study, exercise intervention technique, duration,
20
21 332 outcomes measured, instruments used to measure them, sample size and quality of the study.

22
23
24 333 **(3) Participants data:** type of disease, disease screening tools/diagnostic tools, setting,
25
26 334 inclusion and exclusion criteria, sociodemographic characteristics (e.g. age, ethnicity,
27
28 335 country).

29
30 336 **(4) Outcomes:** definition of adherence and rate of adherence. Adherence was defined as the
31
32 337 percentage of attended sessions during the programs as registered by the instructors in
33
34 338 most studies.¹⁶ Generally considering that participants meet the requirement of adherence
35
36 339 when they complete more than seventy percent sessions of the whole program.⁴⁶⁻⁴⁸ Yet, there
37
38 340 is not an accepted standard for exercise adherence. Grove and Spier defined adherence as the
39
40 341 percentage of older adults who attended ninety percent of sessions.⁴⁹ Keogh et al described
41
42 342 adherence as having attended one course a week over the previous three months.⁵⁰ It
43
44 343 is acknowledged that there is a vast difference in the definition of exercise adherence. We
45
46 344 will describe the meaning of exercise adherence in selected studies. It may be helpful for us
47
48 345 to analyse the differences in research results and make the study more transparent.

49
50 346 The TDF is defined as a priori framework to reflect all coding of data. Coding of data will
51
52 347 include such as authors' descriptions of the results and all relevant quotes from participants
53
54 348 provided in the results section (or results tables) of included studies.⁵¹ We will map the
55
56 349 modifiable facilitators and barriers to exercise adherence as the following 14 domains with 14

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4 350 coding information according to the TDF: (1) Knowledge, (2) Skills, (3) Social influences, (4)
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6 351 Memory, attention and decision processes, (5) Behavioural regulation, (6) Professional/Social
7
8 352 role and identity, (7) Beliefs about capabilities, (8) Belief about consequences, (9) Optimism,
9
10 353 (10) Intentions, (11) Goals, (12) Emotion, (13) Environmental context and resources and (14)
11
12 354 Reinforcement. (15) Any facilitator/barrier that does not match with the existing domains of
13
14 355 the TDF will be organised into the 'Others' as the fifteenth domain.⁵²
15

16 356 In the NVivo.12, we will build three themes in terms of the perspective of the patients,
17
18 357 caregivers and health care professionals to conform to the aim of our study. Each theme will
19
20 358 be divided into two subthemes (modified facilitators and barriers). For each of these
21
22 359 subthemes, we will create 15 domains. For example, if we extract the following text in a
23
24 360 study 'Participant A reported that the intensity of the program was too high that affected
25
26 361 his/her maintenance'. We will code it as 'Goals' in the 14 domains of the TDF. Then we will
27
28 362 compare our coding to generate consensus about identified facilitators and barriers in the
29
30 363 literature. It will be possible that the same sentence will be assigned more than one code. This
31
32 364 process will be undertaken and will be discussed by two researchers (XT Z, HQ C). Any
33
34 365 disagreement between the two researchers will be resolved through further discussion and
35
36 366 adjudication by a third reviewer (J W). When there is a disagreement in the different studies
37
38 367 with the same factor affecting exercise adherence, we will evaluate the characters of the
39
40 368 literature further, including the literature quality, types of research, sample size etc., and
41
42 369 explain potential differences in results across studies. Poor methodological quality will not be
43
44 370 included in the review that will affect the trustworthiness of the synthesis. Meanwhile, this
45
46 371 study will take some measures to minimise all of the potential biases, including providing
47
48 372 the equal weights to the studies with the comparable technical quality, and providing a
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50 373 reasonable justification for not doing so.⁴⁴ We will also try our best to explore the influence
51
52 374 of heterogeneity in this stage of the synthesis process.
53

54 375

56 376 **DISCUSSION**

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4 377 Understanding modifiable facilitators and barriers to exercise adherence for older adults with
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6 378 MCI/dementia is a complex process that needs to be fully explored if we hope to obtain the
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8 379 benefits of exercise intervention in greatest extent. To date, existing research has not studied
9
10 380 this topic. This review will synthesise and report qualitative and quantitative data about
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12 381 exercise adherence in terms of the perspective of patients, caregivers and health care
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14 382 professionals.

15
16 383 This study will have several strengths and implications. First, the results will contribute to
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18 384 understanding the common influencing factors to focus on how to modify barriers best and
19
20 385 enhance facilitators to increase the utility and appeal for the exercise intervention. Second, it
21
22 386 will facilitate sufficient access to care and treatment to help older adults with MCI/dementia
23
24 387 have a broader adoption to exercise intervention. Third, it will have substantial implications
25
26 388 for researchers, clinicians, and policymakers to provide individually tailored care for older
27
28 389 adults with MCI/dementia. We anticipate that this study will also be highly correlated to the
29
30 390 public who want to engage with an exercise program. Last but not least, this systematic
31
32 391 review will be the first try that maps modifiable facilitators and barriers of exercise adherence
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34 392 for older adults with MCI/dementia to the domains of the TDF. In theory, TDF is a
35
36 393 comprehensive framework that synthesises several behaviour change theories, which lower
37
38 394 the risks of missing relevant theoretical constructs or including irrelevant ones.³¹ Hence, it
39
40 395 can be used for summarising the related factors of exercise adherence reported in the previous
41
42 396 studies. The results will also provide a more in-depth insight into the influences on
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44 397 evidence-based behaviour change of exercise adherence. Findings based on the framework of
45
46 398 the TDF can be used to inform the development of effective exercise adherence strategies and
47
48 399 assist practitioners in selecting the most suitable evidence-based exercise programs in clinical
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50 400 settings accordingly.

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53 54 402 **Amendments**

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57 403 If we need to amend this protocol, the date of each amendment will be accompanied by a

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4 404 description of the change and the rationale.
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9 406 **Patient and public involvement**
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11 407 Patients and the public are not involved at this stage of the project.
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16
17 409 **Ethical issues**
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20 410 The systematic review is a retrospective study using publicly available data. As no primary
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22 411 data collection will be undertaken and not requiring a formal ethical assessment and no
23
24 412 informed consent are needed.
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29
30 414 **ACKNOWLEDGEMENTS**
31

32 415 **Conflict of interest**
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34
35 416 All authors declare that we have no conflicts of interest.
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48
49 422 the study nor in the writing of the protocol.
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55 424 **Contributors**
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58 425 All authors contributed to the development of the study design and search strategy. XT Z and
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4 426 LN W designed the study and wrote the protocol. XT Z and H Y wrote the search strategy. H
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6 427 Y, YX C and CX G screened the literature. J W and HQ C checked the selected article. H T
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9
10 429 final protocol.

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13 14 15 431 **REFERENCE**

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Reporting checklist for protocol of a systematic review.

Based on the PRISMA-P guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the PRISMA-Reporting guidelines, and cite them as:

Moher D, Shamseer L, Clarke M, Ghersi D, Liberati A, Petticrew M, Shekelle P, Stewart LA. Preferred Reporting Items for Systematic Review and Meta-Analysis Protocols (PRISMA-P) 2015 statement. Syst Rev. 2015;4(1):1.

	Reporting Item	Page Number
Title		
Identification	#1a Identify the report as a protocol of a systematic review	1
Update	#1b If the protocol is for an update of a previous systematic review, identify as such	n/a not an update

1 **Registration**

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4 [#2](#) If registered, provide the name of the registry (such as 4

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6 PROSPERO) and registration number

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10 **Authors**

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13 **Contact** [#3a](#) Provide name, institutional affiliation, e-mail address of 1-2

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15 all protocol authors; provide physical mailing address of

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17 corresponding author

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20 **Contribution** [#3b](#) Describe contributions of protocol authors and identify 15

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22 the guarantor of the review

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26 **Amendments**

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29 [#4](#) If the protocol represents an amendment of a 15

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31 previously completed or published protocol, identify as

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33 such and list changes; otherwise, state plan for

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35 documenting important protocol amendments

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39 **Support**

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42 **Sources** [#5a](#) Indicate sources of financial or other support for the n/a not included

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44 review

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47 **Sponsor** [#5b](#) Provide name for the review funder and / or sponsor 15

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50 **Role of sponsor** [#5c](#) Describe roles of funder(s), sponsor(s), and / or 15

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52 or funder institution(s), if any, in developing the protocol

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56 **Introduction**

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1	Rationale	#6	Describe the rationale for the review in the context of	4-8
2			what is already known	
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6	Objectives	#7	Provide an explicit statement of the question(s) the	8-9
7			review will address with reference to participants,	
8			interventions, comparators, and outcomes (PICO)	
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14	Methods			
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17	Eligibility criteria	#8	Specify the study characteristics (such as PICO, study	8-10
18			design, setting, time frame) and report characteristics	
19			(such as years considered, language, publication	
20			status) to be used as criteria for eligibility for the review	
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27	Information	#9	Describe all intended information sources (such as	10
28			electronic databases, contact with study authors, trial	
29	sources		registers or other grey literature sources) with planned	
30			dates of coverage	
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37	Search strategy	#10	Present draft of search strategy to be used for at least	10-11
38			one electronic database, including planned limits, such	
39			that it could be repeated	
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45	Study records -	#11a	Describe the mechanism(s) that will be used to manage	12-14
46	data		records and data throughout the review	
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49	management			
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52	Study records -	#11b	State the process that will be used for selecting studies	11
53	selection process		(such as two independent reviewers) through each	
54			phase of the review (that is, screening, eligibility and	
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1		inclusion in meta-analysis)	
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4	Study records -	#11c Describe planned method of extracting data from	11-14
5			
6	data collection	reports (such as piloting forms, done independently, in	
7			
8	process	duplicate), any processes for obtaining and confirming	
9			
10		data from investigators	
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13	Data items	#12 List and define all variables for which data will be	8-9
14			
15		sought (such as PICO items, funding sources), any pre-	
16			
17		planned data assumptions and simplifications	
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21	Outcomes and	#13 List and define all outcomes for which data will be	12-13
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23	prioritization	sought, including prioritization of main and additional	
24			
25		outcomes, with rationale	
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29	Risk of bias in	#14 Describe anticipated methods for assessing risk of bias	11-12
30			
31	individual studies	of individual studies, including whether this will be done	
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33		at the outcome or study level, or both; state how this	
34			
35		information will be used in data synthesis	
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39	Data synthesis	#15a Describe criteria under which study data will be	n/a no meta-
40			analysis or other
41		quantitatively synthesised	statistical
42			analysis
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48	Data synthesis	#15b If data are appropriate for quantitative synthesis,	n/a no meta-
49			analysis or other
50		describe planned summary measures, methods of	statistical
51			analysis
52		handling data and methods of combining data from	
53			
54		studies, including any planned exploration of	
55			
56		consistency (such as I ² , Kendall's τ)	
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1	Data synthesis	#15c	Describe any proposed additional analyses (such as	n/a no meta-
2			sensitivity or subgroup analyses, meta-regression)	analysis or other
3				statistical
4				analysis
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11	Data synthesis	#15d	If quantitative synthesis is not appropriate, describe the	12
12			type of summary planned	
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16	Meta-bias(es)	#16	Specify any planned assessment of meta-bias(es)	n/a no meta-
17			(such as publication bias across studies, selective	analysis or other
18			reporting within studies)	statistical
19				analysis
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26	Confidence in	#17	Describe how the strength of the body of evidence will	n/a
27	cumulative		be assessed (such as GRADE)	
28	evidence			
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Notes:

- 37 • 1b: n/a not an update
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- 40 • 5a: n/a not included
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- 43 • 15a: n/a no meta-analysis or other statistical analysis
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- 46 • 15b: n/a no meta-analysis or other statistical analysis
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- 49 • 15c: n/a no meta-analysis or other statistical analysis
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- 53 • 16: n/a no meta-analysis or other statistical analysis The PRISMA-P checklist is distributed under
- 54 the terms of the Creative Commons Attribution License CC-BY 4.0. This checklist was completed
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