Reviewer's report

Title: Neuropsychological Management of Multiple Sclerosis: Evaluation of a supervised and customized cognitive rehabilitation program for self-used at home (SEPIA): protocol for a randomized controlled trial

Version: 0 Date: 12 Jan 2019

Reviewer: Angie Logan

Reviewer's report:

General feedback

Lots of grammatical errors, which at times makes it difficult to read. Needs more justification in some areas.

Replace "complaint" to "impairment" so it reads cognitive impairment and not cognitive complaint (see comments for Line 40)

You are doing a RCT so use the word "trial" throughout and not "study"

Line by line comments

Line 35: "In this context, we are interested on the efficacy […]" should be "interested in the efficacy". Is this the primary objective? If yes, this needs to be made clear.

Line 40: do people with MS "complain" about their cognition? Consider alternative "who have cognitive impairment" and then add how that is defined, e.g. what severity, because not all people with MS acknowledge or realise they have cognitive impairment.

Line 41: "Patients from experimental group will benefit of the CR program and a psychological support at home during eight weeks". Consider revising as grammatically incorrect. Additionally, the word "benefit" should be changes as this suggests the trial has taken place and results have suggested patients benefit.

Line 45: The Training sessions are described as "fun short exercises". Who determined they were fun? This needs to be referenced when addressing this in the main text.

Line 46: what is the justification for an "active control group"?

Line 48: "various advices", odd phrasing, consider revising
Line 53: "we believe" should be removed and an evidence-based rationale should be provided to justify the trial.

Line 55: "referring practitioners' support should be encouraged" consider revision for something about how this intervention may represent a treatment option for practitioners working with people with MS because you it is important to consider that every intervention is not suitable for all people with MS, and not all people with MS are going to want to use a computer program for their rehab.

Line 90: "young active people to be more […]" what is the age group here? Are you referring to people of working age or a particular age range? Cognitive impairment is prevalent in all ages of people with MS.

Line 93: Consider revising "As well, as current done, assessments does not allow to capture […]" to In addition, current cognitive assessments do not capture real-world […]" as the original sentence is clunky and grammatical incorrect.

Line 99: "[…] most frequently used rehabilitative approaches" Need to consider what the first line treatment or common practice currently is for people with MS. What do clinical guidelines recommend? What profession are you referring to? Occupational Therapists, psychologists as the treatments will differ.

Line 103: "They allow an engaging and fun activity" has this been evidenced? This is a generalisation and potentially some people may not find it fun and engaging.

Line 104: "significantly reducing the costs of rehabilitation". What costs? You need to provide examples of the economic impact.

Line 107: "the control one" should be "the control group".

109-112. You have listed assessments of cognition, e.g. executive functioning but what about functional ability in activities of daily living?

Line 117-118: "The need for better outcomes measures transparency and related ecological validity is also warranted" revise grammar

Line 119-120: "have used different approaches. Broadly speaking, those who aim at increasing cognitive performance and those who rather adopt a holistic approach, intending at improving quality of" revise to "have used two main approaches: those aimed at increasing cognitive performance (include a reference here) and those that adopt a holistic approach (include a reference here), aiming to improve quality"

Line 125: Change "Most of them only aimed" to "Most studies aimed to improve"
Line 126-127: "However, we know that such assessments are […]" change to "However, these assessments are lacking ecological sensitivity and potential improvements"

Line 129: "On theses bases" revise as grammatically incorrect

Line 130: change "at-home program" to "home-based program"

Paragraph starting on Line 129 is a weak justification for qualitative methodology. This needs expanding to justify why qualitative methodology is needed and what it will add to the existing body of literature.

Line 132: change the word complain to impairment throughout the manuscript

Line 132-134 You need to state that these are secondary outcome measures. You also need to justify or explain why you are using these secondary outcome measures.

Line 149: "Orally and written detailed information […]" replace with "Verbal and written information". Also need to provide how the verbal information will be standardised. Will you be using a script?

Line 163: "Definite" to be replaced with "Confirmed" to read "Confirmed diagnosis of MS"

Line 164: Currently states RR and secondary progressive. Should this be or, or and/or?

Line 165: Replace with "Be male or female aged between 18-65 years"

Line 169: replace complaint with impairment throughout

Line 194: "Patients will be removed from the study with no specific procedure". This needs revising as you need a procedure for what you will do if participants get randomised in error, e.g. they don't meet the criteria.

Line 210: references are needed at the end of the sentence "consistency, reliability, reproducibility and acceptability"

Line 229: Is the MCQ-30 self-report or clinician administered? For all outcome measures are they self-completed or will an assessor be asking the questions and the participant reporting?

Line 251: "evaluated during these 3 assessments" change to "at all three time points"

Line 260: "After consent acceptance […]" change to "After patients have provided informed written consent"

Line 279: Need to expand this sentence and state that participants and clinicians are not blinded and why blinding is not possible. Will assessors be blinded?
In the intervention section which starts on Line 307, need to add in that the duration of the intervention period is 8 weeks as currently this is not clear. Again, justification as to why you are using an active control is required.

Given that participants have cognitive impairment and may have problems with problem solving and attention, how much support are they getting with the program?

Line 332: there are quotations marks directly before [29] is this a mistake?

Paragraph that is line 335-337. No mention of fatigue and how this is accounted for. Given that fatigue is prevalent in people with MS this needs to be mentioned.

Line 338: "Then participants will underwent" needs changing to "undergo"

Line 340: Why is the intervention period 8 non-consecutive weeks. This needs justifying.

Line 343: "to promote coping strategies […]" this needs to be more explicit

Line: 350: "management to attest any improvement" Wil patients who are fatigued going to be given opportunity to break or rest during the assessment session?

Line 352: change underwent to undergo

Lines 358-360: would be helpful to the reader to refer to the schedule of events table to see what outcome measures you propose.

Lin 372: What are you basing the potential drop outs of 20 patients on? Need to provide evidence-based justification for this number.

Line 376: You need to provide a reference for the intention-to-treat analysis and per-protocol analysis and justify why you are using both.

Line 378: provide a reference for SPSS.

Line 382: consider revising to: "To date, pharmacological treatment has not improved"

Line 383-384: Yet, as patients are keen for care support" this whole sentence needs revising as does not make sense. Also, what is care support?

Line 384-385: Consider revising to "Such conclusions warrant prioritisation of non-pharmacological, pragmatic, ecological, low-cost alternatives that address difficulties"

Line 386-387: Need to justify and reference the statement "computer-assisted CR may bring flexibility, dynamics, objectivity, ecological validity […]"

Line 391-392 change "wellbeing to our MS patients" to "wellbeing to people with MS"
Lines 395-397: whole sentence starting "Hence […] needs revising as does not make sense

Line 402-403: Consider revising to: "A home-based CR computer program provides advantages over clinic-based training […]"

Line 407-408: "interviews with professional training may […]" to "support or guidance with a professional trainer may help participants overcome cognitive disturbances […]". Unsure what you mean by "develop personal abilities by themselves".

Line 410: Reference 3. What did it find? This sentence from Line 408-410 starting "Feasibility and acceptability […]" needs revising for grammar as well as adding what the outcome of the paper was.

Paragraph that starts line 411 and ends 417 needs revising as grammar is poor

Line 416: "can affect outcomes and thereby their generalization in daily life". Aside from the poor grammar, need to explain if the effects are positive or negative.

Paragraph starting line 418 to 421 is difficult to understand and grammar is poor. Needs revising. What does "find their best path" mean on line 420? Lin 421 what does "educated patients" mean?

Line 422 at the end change "existent" to "existing"

Line 423: revise to "and provide new evidence for improving QoL […]"

Line 424: "promote personal benefit" need to give an example and explain this further.

Line 426: You state you "expect to make this CR program more extensively available", consider revising to "anticipate".

Line 427: "to anyone interested", are you aiming the program at people with MS directly or via clinicians who are working with people with MS in both hospitals and community settings?

Line 429: Sounds like you are focusing just on MS care centres. This may be appropriate for your country but need to consider international relevance as this is not necessarily true in the UK.

Line 429-431 "Indeed, we must be able to propose rehabilitation to any patient in demand who cannot enter a study because of the strict inclusion-exclusion criteria" needs revising as does not make sense.

Line 434: need to add in the date the first participant was recruited.

Comments about the table at the back with the visits and outcome measures on:

Baseline assessment is not clear from the list of visits.
According to the main text, MUSIQoL is used at baseline, after 1 week and 6 months yet is only listed once in the table (line 211).

Weeks and months appear to be used interchangeably with regards to trial timelines. Need to be consistent and choose either weeks or months, not both.

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