PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: Protocol for a single-case experimental design with multiple baselines
AUTHORS	Lindstad, Marte; Obstfelder, Aud; Sveen, Unni; Stigen, Linda

VERSION 1 – REVIEW

REVIEWER	Manolov, Rumen University of Barcelona
REVIEW RETURNED	27-Jan-2022

GENERAL COMMENTS	I appreciate the possibility to review the manuscript entitled "Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: Protocol for a single-case experimental design with multiple baselines" submitted for publication to BMJ Open. My review will focus on methodological and statistical aspects, as I am not an expert in the substantive topic (brain injury in older adults, cognitive challenges, and community-based rehabilitation). The manuscript presents the following strengths: 1. The importance of the research question (incl. the target population, meaningful improvement in everyday life functioning) is sufficiently justified. 2. Using a single-case design that entails a replication over six participants. 3. Applying the SPENT checklist for reporting protocols and the RoBiNT scale for assessing the methodological rigor of the design and procedure. 4. Intention to use the SCRIBE reporting guidelines for the manuscript to be developed when the planned study is eventually performed. 5. Having discussed the research with relevant stakeholders (stroke victims and occupational therapists using the standardized intervention to be studied). 6. Providing information about the setting. 7. Using generalization measures, which are relevant for social validity. 8. Including blinded rating and inter-rater reliability. 9. Combining visual inspection of the graphed data with quantifications and evaluation of clinical significance. In order to improve the manuscripts, the authors could take into consideration the following aspects related to content:

	1. In relation to Page 3, Article summary – it is correct to note that generalization could be compromised in the context of a single-case design, although replication is also necessary for external validity in the context of group-design studies in absence of random sampling. In order to avoid being too critical with the external validity (or other supposed limitations of the single-case designs, as compared to group design studies in which a generalization from aggregates/averages to individual participants may not be warranted), I recommend consulting the following sources: Kazdin (2021), Walker and Carr (2021), and Zuidersma et al. (2020). Specifically, multiple-baseline designs require at least three participants for internal validity – for having enough opportunities to test for the presence of an intervention effect (Kratochwill et al., 2013; What Works Clearinghouse, 2020), so the "second set" of three participants (for a total of six) could be considered the one contributing to external validity. Thus, replication in a multiple-baseline design is not only for external validity. Kazdin, A. E. (2021). Single-case experimental designs: Characteristics, changes, and challenges. Journal of the Experimental Analysis of Behavior, 115(1), 56-85. https://doi.org/10.1002/jeab.638 Kratochwill, T. R., Hitchcock, J. H., Horner, R. H., Levin, J. R., Odom, S. L., Rindskopf, D. M., & Shadish, W. R. (2013). Single-case intervention research design standards. Remedial and Special Education, 34(1), 26−38. https://doi.org/10.1177/0741932512452794 Walker, S. G., & Carr, J. E. (2021). Generality of findings from single-case designs: It's not all about the "n." Behavior Analysis in Practice, 14(4), 991–995. https://doi.org/10.1007/s40617-020-00547-3 What Works Clearinghouse. (2020). What Works Clearinghouse Standards Handbook, Version 4.1. U.S. Department of Education, Institute of Education Sciences, National Center for Education Evaluation and Regional Assistance. Retrieved from https://ies.ed.gov/ncee/wwc/Docs/referenceresources/WWC-Standards-Handbook-v4-1-508.pdf Zuidersma, M., Riese, H., Snippe, E., Booij, S. H., Wichers, M., & Bos, E. H. (2020). Single-subject research in psychiatry: Facts and fictions. Frontiers in Psychiatry, 11, 1174. https://doi.org/10.3389/fpsyt.2020.539777 2. In relation to Page 3, Article summary – If visual analysis is judged to be too subjective, formal decision rules can be used (e.g., Fisher et al., 2003; Manolov & Vannest, 2019; Pfadt & Wheeler, 1995) or at least visual aids and quantifications (Lane & Gast, 2014). Fisher, W. W., Kelley, M. E., & Lomas, J. E. (2003). Visual aids and structured criteria for improving visual inspection and interpretation of single-case designs. Journal of Applied Behavior Analysis, 36(3), 387–406. https://doi.org/10.1901/jaba.2003.36-387 Lane, J. D., & Gast, D. L. (2014). Visual analysis in single case experimental design studies: Brief review and guidelines. Neuropsychological Rehabilitation, 24(3-4), 445–463. https://doi.org/10.1080/09602011.2013.815636

	Manolov, R., & Vannest, K. (2019). A visual aid and objective rule encompassing the data features of visual analysis. Behavior Modification. Advance online publication. https://doi.org/10.1177/0145445519854323 Pfadt, A., & Wheeler, D. J. (1995). Using statistical process control to make data-based clinical decisions. Journal of Applied Behavior Analysis, 28(3), 349-370. https://doi.org/10.1901/jaba.1995.28-349 3. Page 5, Rationale for trail design – Maybe it is not necessary to use the term “power”, as it is implicitly associated with “statistical power” (especially when referring to the number of participants or measures) and obtaining statistically significant results is usually not the aim of SCED research (Branch, 2014; Iversen, 2021; Perone, 1999). Using visual analysis and descriptive statistics, as suggested in the current protocol, means that statistical significance is also not relevant for the current research. Therefore, a different wording is to be found. Branch, M. (2014). Malignant side effects of null-hypothesis significance testing. Theory & Psychology, 24(2), 256-277. https://doi.org/10.1177/0959354314525282 Iversen, I. H. (2021). Sidman or statistics?. Journal of the Experimental Analysis of Behavior, 115(1), 102-114. https://doi.org/10.1002/jeab.660 Perone, M. (1999). Statistical inference in behavior analysis: Experimental control is better. The Behavior Analyst, 22(2), 109-116. https://doi.org/10.1007/BF03391988 4. Page 5, Rationale for trail design – It is necessary to make clear (or modify) what is mean by “at least five data collection points within four phases”. In each tier (A-B comparison) in a multiple-baseline design, the recommendation is for five measurements, but there is no need for four phases, as in each tier (e.g., for each participant in a multiple-baseline design across participants) there are only two phases. Four phases are required in a reversal design (e.g., A-B-A-B). 5. Page 5, Intervention to be studied / Page 11, Procedural fidelity – Some more details are required regarding the kinds of checks planned for intervention / procedural fidelity (Ledford & Gast, 2014). Ledford, J. R., & Gast, D. L. (2014). Measuring procedural fidelity in behavioural research. Neuropsychological Rehabilitation, 24(3-4), 332-348. https://doi.org/10.1080/09602011.2013.861352 6. Page 6, Participants, recruitment, and inclusion criteria – Information is lacking regarding age as an inclusion criterion. Maybe it is assumed that the study is performed with people you are 65 or older. 7. Page 7, Description and documentation of ‘treatment as usual’ – given the name of this section (i.e., the word ‘description)’, apparently some details need to be provided regarding what this ‘treatment as usual’ includes, beyond stating that “During all phases, the participants will receive ‘treatment as usual’”. 8. Page 8, Generalization measures – Due to my lack of knowledge

	on the topic, it is not clear to me whether the modified version of the Barthel index has already been presented and justified in reference 48 (Collin et al., 1988), or it is something novel that the authors are proposing as part of their study (and thus requires additional justification). 9. Page 8, Procedure – It is unclear how the sentence "Randomization to length of baseline phase, that serves as control data in this design, is recommended by RoBiNT" is related to the previous sentences in which randomization is not mentioned. Will randomization be used or not? 10. Page 8, Procedure – On Page 5 it is mentioned "At least five data collection points within four phases and a minimum of three participants is recommended to meet design quality standards", but from Page 8 it appears that for one of the tiers there will be only three measurements in the baseline. Thus, it is not clear why the sentence on Page 5 should appear, if the recommendation is not followed. 11. Page 9, The intervention phases – Considering the information provided in the text ("5 points", line 39) and in Table 1 ("9 sessions PRPP intervention"), it would be desirable to state explicitly (or more clearly) how many measurement occasions are planned for the intervention phase. 12. Page 9, The post-intervention phases – As in the previous comment, it is necessary to state explicitly how many measurement occasions are planned for the post-intervention phase. 13. Page 9, The follow-up phases – The measurements to be taken are presented as "generalization" and I wonder whether they could also be considered "maintenance" measures of the effects (expected to be) observed during the intervention and post-intervention phases. 14. Page 10, Data analysis plan – Given that the visual inspection of the detail entails assessing several data features (the results about which may not coincide), the authors need to explicitly state whether they have some expectations regarding the effect (e.g., whether it is expected to be immediate or delayed, abrupt as a change in level or progressive as a change in slope or trend, see Manolov et al., 2021). Such explicitly stated expectations could be useful in case differences are not observed in all data features (level, trend, variability, immediacy, overlap). Manolov, R., Moeyaert, M., & Fingerhut, J. (2021). A priori justification for effect measures in single-case experimental designs. Perspectives on Behavior Science. Advance online publication. https://doi.org/10.1007/s40614-021-00282-2 15. Page 10, Data analysis plan – In the Abstract it is mentioned that descriptive statistics will be used, but in the "Data analysis plan" there are no indications provided. Perhaps the authors mean that they will use the quantifications suggested by Lane and Gast (reference 49 in the manuscript), but they still need to be explicit about which these measures are and why they consider them to be useful or appropriate. Justifications are crucial (Tincani & Travers, in press).

	Tincani, M., & Travers, J. C. (in press). Questionable research practices in single-case experimental designs: Examples and possible solutions. In W. O'Donohue, A. Masuda, & S. O. Lilienfeld (Eds.). Questionable research practices: Designing, conducting, and reporting sound research in clinical psychology. Cham, Switzerland: Springer Publications. Retrieved from https://www.researchgate.net/publication/355866412_Questionable_Research_Practices_in_Single-Case_Experimental_Designs_Examples_and_Possible_Solutions 16. Page 10, Data analysis plan – The authors need to be explicit regarding whether the same aspects will be visually assessed and whether the same quantifications will be provided for comparing baseline vs. intervention, and also for intervention vs. post-intervention, and follow-up vs. post-intervention. According to the number of measurements expected in each of these phases / moments, the kind of visual or quantitative assessment to be performed is likely to be different. 17. Page 10, Data analysis plan – The authors could consider using multilevel models for quantifying the amount of change between the baseline and the intervention phase (Ferron et al., 2009, 2010), for instance using MultiSCED (http://34.251.13.245/MultiSCED/; Declercq et al., 2020) or https://manolov.shinyapps.io/SeveralAB/. Such an analysis can provide both overall quantifications for all six participants and individual estimates of the intervention effect (overall change in level or immediate change in level plus change in trend). Moreover, such methods can handle autocorrelation (item 20a2 from SPENT 2019). Similarly, in relation to potential missing data (item 20c in SPENT 2019), the authors could consult Peng and Chen (2021), in case there is a possibility for missing data. Declercq, L., Cools, W., Beretvas, S. N., Moeyaert, M., Ferron, J. M., & Van den Noortgate, W. (2020). MultiSCED: A tool for (meta-)analyzing single-case experimental data with multilevel modeling. Behavior Research Methods, 52(1), 177–192. https://doi.org/10.3758/s13428-019-01216-2 Ferron, J. M., Bell, B. A., Hess, M. R., Rendina-Gobioff, G., & Hibbard, S. T. (2009). Making treatment effect inferences from multiple-baseline data: The utility of multilevel modeling approaches. Behavior Research Methods, 41(2), 372-384. https://doi.org/10.3758/BRM.41.2.372 Ferron, J. M., Farmer, J. L., & Owens, C. M. (2010). Estimating individual treatment effects from multiple-baseline data: A Monte Carlo study for multilevel-modeling approaches. Behavior Research Methods, 42(4), 930-943. https://doi.org/10.3758/BRM.42.4.930 Peng, C. Y. J., & Chen, L. T. (2021). Assessing intervention effects in the presence of missing scores. Education Sciences, 11(2), article 76. https://doi.org/10.3390/educsci11020076 18. In relation to item 12 of the reviewer checklist in BMJ Open, the authors do not explicitly discuss any (expected) limitations of the study (e.g., having fewer than five measurements in the baseline phase for some tiers; not using a concurrent multiple baseline design, which would allow for a comparison between-series: see Ferron et al., 2014).

	Ferron, J. M., Moeyaert, M., Van den Noortgate, W., & Beretvas, S. N. (2014). Estimating causal effects from multiple-baseline studies: Implications for design and analysis. Psychological Methods, 19(4), 493-510. http://dx.doi.org/10.1037/a0037038 Formal aspects: 1. Page 3, Article summary – replace “systematically replications” by “systematic replications”. 2. Page 5, Research question 3 – maybe the question “How effective is task mastery” can be modified to something along the lines “To what extent is task mastery maintained … four weeks after discharge to home” 3. Page 5, Research question 4 – maybe the question “How effective is the cognitive strategy application” can be modified to something along the lines “To what extent is the cognitive strategy application maintained and generalized … four weeks after discharge to home” 4. Page 6, Intervention to be studied – although it is implicit in the text, the authors could make it explicit that reference 24 (Chapparo C, Ranka J. The PRPP Intervention Course Manual, 2018.) is the manual for the intervention and that the intervention will be carried out according to this manual.

REVIEWER	Watter, Kerrin Princess Alexandra Hospital Health Service District, ABI TRS
REVIEW RETURNED	22-Feb-2022

GENERAL COMMENTS	**Review of PRPP protocol** I would like to commend your team on a very well written protocol, and an excellently structured SCED intervention. Clinically, I see the OTs in my team use the PRPP during community rehabilitation for younger adults with ABI. I am pleased to see this tool being used in a research study in this manner, and I look forward to seeing the results in the future. My review comments below relate to the methods and analysis sections of your protocol - my queries and suggestions will help clarify certain areas for the reader. **Setting** You provide a detailed setting of the rehabilitation services offered across the two municipalities (with different services / units available within the health centres – e.g., assessment unit, short stay unit). It is unclear whether clients are being recruited from a specific unit / area, or from all available services / units. Could this please be clarified? This will also help readers to better understand the demographics of your selected population and their phase of recovery for your study. ***Intervention to be studied*** You provide excellent detail regarding the PRPP intervention and assessment, and information on how you will address reliability and fidelity. A point to consider highlighting in your protocol is the fact that the PRPP requires clinicians to be trained and assessed as competent in the intervention and assessment methods, and this process should help support delivery of the intervention across treating therapists (in addition to the processes and SCED procedures you are undertaking). **Blind rating and inter-rater reliability**

	Please clarify the procedure for your blinded assessment and inter-rater reliability further. Are all the assessment conditions recorded and only 20% watched? Or are only 20% being recorded to be watched? Also - who is doing the recording - please clarify who records this (e.g., treating OT). **Procedure** Your comment on randomization needs clarifying - you state that randomization to length of baseline phase (control in your design) is recommended in the RoBiNT protocol. However, you do not state whether you are actively doing this and achieving randomisation (or how), or not. From your methods, I cannot find a statement regarding randomise a client to the determined baseline (e.g., Tier 1, 2, or 3). ***The intervention phase:*** When you state the interdisciplinary team or relatives may prompt and give cues on the PRPP intervention, how and when will this be observed (e.g., is this within treatment sessions or external to this)? And how do you plan to measure this? **Procedure / data analysis plan** Could you please clarify (either in data collection or data analysis section) whether the PRPP data for each of the 5 activities (for each participant) will be presented and analysed separately, or is the data to be collapsed and reported overall? This was unclear to me in your procedure, and will impact analysis. **Replication / generalisation** I became confused with your plans for replication vs earlier plans for participant recruitment. In this section, it seems you will replicate the study with 3 participants from each municipality (A and B). However, earlier in the methods you state that any patient meeting criteria will be considered for inclusion (seeking 6 participants) – will this achieve the desired numbers and location for replication? Your processes will benefit from some clarification in regard to study recruitment numbers (n=6), their location (e.g., A vs B; number per location) including numbers for replication. If you plan to recruit 3 participants from each municipality, this needs to be stated earlier. Also, you state that more systematic replication will occur according to number of admissions. Does this mean you are seeking a sample of >6? **Procedural fidelity** Is the procedure checklist being developed just for the treatment sessions, or for the entire protocol? Do you plan to rate fidelity, and will this involve independent assessors also? These are points worth clarifying here. Lastly, please double-check your page references on the SPENT checklist – a few seem to have changed. Thank you for the opportunity to review your paper. I hope the comments above help clarify your protocol methodology for publication; I recommend these minor revisions be addressed prior to acceptance.

REVIEWER	Kettlewell, Jade University of Nottingham, Centre for Health Innovation, Leadership & Learning

REVIEW RETURNED	23-Feb-2022

GENERAL COMMENTS	Thank you for inviting me to review this manuscript. The authors present a protocol for a trial to investigate the effectiveness of the Perceive, Recall, Plan and Perform System (PRPP) for older adults with ABI. The PRPP is a standardised way of assessing and exploring how effective a patient is at applying cognitive strategies to various tasks. The authors have chosen a single case experimental design, for which a rationale is provided. The manuscript is well written and concise considering the complexity of the proposed trial and intervention. The methods are described in a detailed and clear way to enable replication. I have a some minor suggestions, which I hope the authors will consider. Page numbers refer to pages in the pdf proof. Abstract Page 2, line 32: It would be good to have an indication of what you mean by older adults, it could simply be (i.e. over 65) or (aged 65+) etc. The definition of 'older adult' varies so it is good to give the reader an idea of the population you are investigating. Page 2, line 40: You state 'persons' but it would be better if you stated 'older adults' here for consistency in population. Page 3, line 15: Expand MDBs Page 3, line 36-37: Consider rewording sentence as I misread the first time, suggest the following, 'It is essential (or you could use important) that these patients are both empowered and able to reach their maximum level of independence for a sustainable health service system'. Page 4, line 42: 'evaluate occupational performance and train mastery...' it would be useful to have a very brief definition of 'task mastery' after this statement. You could put it in brackets before next sentence. I appreciate readers will understand what mastery means in an everyday context, but what does it mean in the context of your trial/intervention? Page 4, line 52: 'older clients', why have you changed from patients to clients? Keep it consistent. Page 4, line 58: Add age range after 'older adults'. See comment about abstract. Page 5, line 36-39: Is there reason for not choosing a RCT linked to limited OTs being trained in PRPP or is the reason because you wouldn't be able to identify enough patients through those OTs working in the community. This is a confusing statement as you have presented two ideas. It would be good if you could expand on this and explain why a RCT is not an option. You might have to briefly describe how patients will be identified/initial contact if it is the trained OTs that will limit your ability to recruit patients. Page 6, line 7-8: Did you speak to patient representatives from the stroke association you mention, if so how many? Did you speak to any carers? Page 6, lines 24-27: font looks different here, please amend

	Page 6, lines 41-42: You state 'any patient admitted to a health centre with an ABI will be considered...' - are there any specific inclusion criteria? I know I have mentioned before, but it would be good to have repetition of the age criteria here as it isn't clear whether these health centres accept patients that are younger than 65 years. Page 6, line 48: 'more challenging tasks' please provide an example of what this would involve. Page 6, line 55: As mentioned before, provide a definition of 'mastery'. You may think it is more appropriate to add this here rather than above (see previous comment). Page 7, line 26: Will you be collecting any data about 'usual care'? if so, please add information about this. General comments: 1. Will you be involving any patient/service user representatives to support the running of your trial? For example, will they be involved in developing patient facing information or will they be involved in any of the analysis? 2. How will you ensure diversity in your sample?

VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

Dr. Rumen Manolov, University of Barcelona Comments to the Author:
I appreciate the possibility to review the manuscript entitled "Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: Protocol for a single-case experimental design with multiple baselines" submitted for publication to BMJ Open.

My review will focus on methodological and statistical aspects, as I am not an expert in the substantive topic (brain injury in older adults, cognitive challenges, and community-based rehabilitation).

The manuscript presents the following strengths:
1. The importance of the research question (incl. the target population, meaningful improvement in everyday life functioning) is sufficiently justified.
2. Using a single-case design that entails a replication over six participants.
3. Applying the SPENT checklist for reporting protocols and the RoBiNT scale for assessing the methodological rigor of the design and procedure.
4. Intention to use the SCRIBE reporting guidelines for the manuscript to be developed when the planned study is eventually performed.
5. Having discussed the research with relevant stakeholders (stroke victims and occupational therapists using the standardized intervention to be studied).
6. Providing information about the setting.
7. Using generalization measures, which are relevant for social validity.
8. Including blinded rating and inter-rater reliability.
9. Combining visual inspection of the graphed data with quantifications and evaluation of clinical significance.
Response: Thank you for encouraging comments and further, for the insightful reviews and recommended readings.

In order to improve the manuscripts, the authors could take into consideration the following aspects related to content:

1. In relation to Page 3, Article summary – it is correct to note that generalization could be compromised in the context of a single-case design, although replication is also necessary for external validity in the context of group-design studies in absence of random sampling. In order to avoid being too critical with the external validity (or other supposed limitations of the single-case designs, as compared to group design studies in which a generalization from aggregates/averages to individual participants may not be warranted), I recommend consulting the following sources: Kazdin (2021), Walker and Carr (2021), and Zuidersma et al. (2020). Specifically, multiple-baseline designs require at least three participants for internal validity – for having enough opportunities to test for the presence of an intervention effect (Kratochwill et al., 2013; What Works Clearinghouse, 2020), so the "second set" of three participants (for a total of six) could be considered the one contributing to external validity. Thus, replication in a multiple-baseline design is not only for external validity.

Response: Thank you for the feedback and the recommended readings. We will make the text more precise by changing the sentence slightly. After adding information in the discussion chapter, we also add another limitation: 'The practice settings combined with ethical concerns for persons with newly acquired brain injury can influence methodological recommendations.'

2. In relation to Page 3, Article summary – If visual analysis is judged to be too subjective, formal decision rules can be used (e.g., Fisher et al., 2003; Manolov & Vannest, 2019; Pfadt & Wheeler, 1995) or at least visual aids and quantifications (Lane & Gast, 2014).
Response: Will be changed into: Visual analyses are criticized for being subjective; therefore, visual aids and quantifications will be applied. We also restructured and added information under the sub-heading 'Data analysis plan' (p. 7-8).

3. Page 5, Rationale for trail design – Maybe it is not necessary to use the term "power", as it is implicitly associated with "statistical power" (especially when referring to the number of participants or measures) and obtaining statistically significant results is usually not the aim of SCED research (Branch, 2014; Iversen, 2021; Perone, 1999). Using visual analysis and descriptive statistics, as suggested in the current protocol, means that statistical significance is also not relevant for the current research. Therefore, a different wording is to be found.
Response: Experimental control is chosen over the word power and changed in the text (p.3).

4. Page 5, Rationale for trail design – It is necessary to make clear (or modify) what is mean by "at least five data collection points within four phases". In each tier (A-B comparison) in a multiple-baseline design, the recommendation is for five measurements, but there is no need for four phases, as in each tier (e.g., for each participant in a multiple-baseline design across participants) there are only two phases. Four phases are required in a reversal design (e.g., A-B-A-B).
Response: This will be modified into 'At least five data collection points within *each phase* and a minimum of three participants is recommended to meet design quality standards' (p. 3).

5. Page 5, Intervention to be studied / Page 11, Procedural fidelity – Some more details are required regarding the kinds of checks planned for intervention / procedural fidelity (Ledford & Gast, 2014).
Response: Under the sub-heading 'Procedural fidelity' (p. 8) we have clarified what Ledford & Gast (2014) call procedural fidelity: to what degree the research plan was implemented as intended. We can see that treatment fidelity is not outspoken, and we will explain why we do not have an explicit treatment fidelity checklist. As mentioned in the chapter 'The intervention phases' (p.7) an intervention plan is developed for each participant.

We also changed the text from 'A checklist is made for the OT to follow and high fidelity is suggested by at least 80% agreement with the procedure checklist [31]' into

'A checklist for the entire protocol is made, where the treating OTs mark the steps as completed or not. This checklist is assessed by the first author, and high fidelity is suggested by at least 80% agreement with the procedure checklist [31]' (p. 8) and further, we added

'The treatment sessions are highly individualized to the participant and the context and are not externally assessed for fidelity. The fact that the OTs need PRPP training and assessed as competent supports delivery of the interventions across the treating OTs' (p.8).

Ledford, J. R., & Gast, D. L. (2014). Measuring procedural fidelity in behavioural research. Neuropsychological Rehabilitation, 24(3-4), 332-348. https://doi.org/10.1080/09602011.2013.861352

6. Page 6, Participants, recruitment, and inclusion criteria – Information is lacking regarding age as an inclusion criterion. Maybe it is assumed that the study is performed with people you are 65 or older.
Response: We have made changes under 'Participants, recruitment, and inclusion criteria' (p. 4): Any client admitted to the health centre with an ABI *that is referred to OT services* will be considered for inclusion *in the trial by their OT*. In this way, we follow ordinary practice and do not exclude clients because of their age; however, since we started the dialogue with the OTs, all their clients were older adults (65+).

Further response can be read under reviewer 2's comment on 'Setting' (p.4).

7. Page 7, Description and documentation of 'treatment as usual' – given the name of this section (i.e., the word 'description)', apparently some details need to be provided regarding what this 'treatment as usual' includes, beyond stating that "During all phases, the participants will receive 'treatment as usual'".
Response: We have changed the name of the section and made major changes in the text to make the information more transparent (p. 5).

8. Page 8, Generalization measures – Due to my lack of knowledge on the topic, it is not clear to me whether the modified version of the Barthel index has already been presented and justified in reference 48 (Collin et al., 1988), or it is something novel that the authors are proposing as part of their study (and thus requires additional justification).
Response: Today the modified version is the one used in the practice settings we know, and also in the ordinary rehabilitation setting in this study. The reference 47 (Mahoney & Barthel, 1965) are to honour the right source for The Barthel Index. From 1988, as explained in the referece 48 (Collin et al 1988), the scoring system changed. The sentence 'In a modified version, to make the scoring easier and more intuitive' is changed into '*The participants score 0, 1 or 2 points and a* maximum score of 20 indicates independence…..' (p. 6) with the reference 48 (Collin et al 1988). This is done to have the right reference for this scoring, but without confusing the reader.

9. Page 8, Procedure – It is unclear how the sentence "Randomization to length of baseline phase, that serves as control data in this design, is recommended by RoBiNT" is related to the previous sentences in which randomization is not mentioned. Will randomization be used or not?
Response: The word 'given' will be changed into 'randomized to' in the two previous sentences (p. 6) to clarify. "Randomization to length of baseline phase, that serves as control data in this design, is recommended by RoBiNT" is changed into 'Randomization to length of baseline phase is recommended by RobiNT', because the information '…that serves as control data in this design' does not really belong to this section.

10. Page 8, Procedure – On Page 5 it is mentioned "At least five data collection points within four phases and a minimum of three participants is recommended to meet design quality standards", but from Page 8 it appears that for one of the tiers there will be only three measurements in the baseline. Thus, it is not clear why the sentence on Page 5 should appear, if the recommendation is not followed.
Response: There are still meant to be five measure points, even if the baseline phase is three days. We consider it to be unethical to hold back intervention for more than 7 days. To have some gap/range between the different tiers we consider that we need a minimum of two days. We have tried to make that distinction clear by using three, five or seven *days*, but five measure *points* (p. 7).

11. Page 9, The intervention phases – Considering the information provided in the text ("5 points", line 39) and in Table 1 ("9 sessions PRPP intervention"), it would be desirable to state explicitly (or more clearly) how many measurement occasions are planned for the intervention phase.
Response: There are 9 interventions in the intervention phase, but the measurements does not occur every intervention session (because of the workload for the treating OTs), and therefore we stick to the recommendations of five occasions measured. The last sentence is changed to from '….and 2 at 5 points in the intervention phase' into
'… and 2 at *five* points *during* the intervention phase' as a try to make it clearer (p. 7).

12. Page 9, The post-intervention phases – As in the previous comment, it is necessary to state explicitly how many measurement occasions are planned for the post-intervention phase.
Response: To state more explicit how many measurement occasions are planned, the sentence …'the same five tasks will be measured without the PRPP intervention to assess if the patient has internalized the strategies' is changed into
…*'there will be five measurements of the same tasks* without intervention to assess if the participant has internalized the strategies' (p. 7).

13. Page 9, The follow-up phases – The measurements to be taken are presented as "generalization" and I wonder whether they could also be considered "maintenance" measures of the effects (expected to be) observed during the intervention and post-intervention phases.
Response: We propose the generalization to other activities also should be considered. The sentence is changed from 'This is to measure whether the participant has generalized the cognitive strategy application to a variety of everyday tasks and contexts' into
'This is to measure whether the *observed effects from the intervention and post-intervention phase persists and whether the cognitive strategy application is generalized* to a variety of everyday tasks and contexts' (p.7).

14. Page 10, Data analysis plan – Given that the visual inspection of the detail entails assessing several data features (the results about which may not coincide), the authors need to explicitly state whether they have some expectations regarding the effect (e.g., whether it is expected to be immediate or delayed, abrupt as a change in level or progressive as a change in slope or trend, see Manolov et al., 2021). Such explicitly stated expectations could be useful in case differences are not observed in all data features (level, trend, variability, immediacy, overlap).
Response: The recommended article was very interesting and clarifying, and the flowchart will be used when planning future projects. We have added this information: 'The expected data pattern is variability between the tasks, and an immediate improvement is expected when the intervention is introduced; further, it is expected that the strategies are internalized and therefore a persistent positive trend in the post-intervention and follow-up phases will be shown' (p.7).

Manolov, R., Moeyaert, M., & Fingerhut, J. (2021). A priori justification for effect measures in single-case experimental designs. Perspectives on Behavior Science. Advance online publication. https://doi.org/10.1007/s40614-021-00282-2

15. Page 10, Data analysis plan – In the Abstract it is mentioned that descriptive statistics will be used, but in the "Data analysis plan" there are no indications provided. Perhaps the authors mean that they will use the quantifications suggested by Lane and Gast (reference 49 in the manuscript), but they still need to be explicit about which these measures are and why they consider them to be useful or appropriate. Justifications are crucial (Tincani & Travers, in press).
Response: Thank you for showing us the very clarifying article of Tincani & Travers. The content could be used for more than understanding why the analyse methods must be clear and with justification in the protocol before starting data collection. We will add to the text: 'The mean and median values are described for all tasks collapsed and changes described between the phases for both primary and secondary outcomes to compare to the examination of the visual inspections' (p. 8).

Tincani, M., & Travers, J. C. (in press). Questionable research practices in single-case experimental designs: Examples and possible solutions. In W. O'Donohue, A. Masuda, & S. O. Lilienfeld (Eds.). Questionable research practices: Designing, conducting, and reporting sound research in clinical psychology. Cham, Switzerland: Springer Publications. Retrieved from https://www.researchgate.net/publication/355866412_Questionable_Research_Practices_in_Single-Case_Experimental_Designs_Examples_and_Possible_Solutions

16. Page 10, Data analysis plan – The authors need to be explicit regarding whether the same aspects will be visually assessed and whether the same quantifications will be provided for comparing baseline vs. intervention, and also for intervention vs. post-intervention, and follow-up vs. post-intervention. According to the number of measurements expected in each of these phases / moments, the kind of visual or quantitative assessment to be performed is likely to be different.

Response: Under point 10 we have clarified that there will be five measurements in each phase. Major revisions are made regarding transparency in 'Data analysis plan' (p. 7-8). The text is adjusted to be more explicit: 'Both graphs will be analysed to determine if there is an immediate change in the target behaviour from *the baseline to the intervention phase'* and major changes of the following information: 'Furthermore, if the expected trends drop, persist, or increase when measured without intervention in the post-intervention. The follow-up measurements will be compared to the post-intervention data for maintenance of task mastery and a presumable internalization of the cognitive strategies. The cognitive strategy application will be analysed if they are applied in the two new and untrained activities compared to the five trained activities.'

Clinical significance is described in the last section of this chapter.

17. Page 10, Data analysis plan – The authors could consider using multilevel models for quantifying the amount of change between the baseline and the intervention phase (Ferron et al., 2009, 2010), for instance using MultiSCED (http://34.251.13.245/MultiSCED/; Declercq et al., 2020) or https://manolov.shinyapps.io/SeveralAB/. Such an analysis can provide both overall quantifications for all six participants and individual estimates of the intervention effect (overall change in level or immediate change in level plus change in trend). Moreover, such methods can handle autocorrelation (item 20a2 from SPENT 2019). Similarly, in relation to potential missing data (item 20c in SPENT 2019), the authors could consult Peng and Chen (2021), in case there is a possibility for missing data.
Response: Thank you so much for sharing these useful resources with us.

18. In relation to item 12 of the reviewer checklist in BMJ Open, the authors do not explicitly discuss any (expected) limitations of the study (e.g., having fewer than five measurements in the baseline phase for some tiers; not using a concurrent multiple baseline design, which would allow for a comparison between-series: see Ferron et al., 2014).
Response: To explicitly discuss expected limitations in the study we have made changes to this section (p. 9). Information is added with these two sentences:

'Concurrent baseline phases are preferred, but in this chosen real-world setting, this is not possible.'

'We are aware that the everchanging practice setting combined with the participants' very different needs and expectations to rehabilitation can threaten the methodological recommendations.'

Formal aspects:
1. Page 3, Article summary – replace "systematically replications" by "systematic replications". Response: Replaced (p.1).
2. Page 5, Research question 3 – maybe the question "How effective is task mastery" can be modified to something along the lines "To what extent is task mastery maintained … four weeks after discharge to home"
3. Page 5, Research question 4 – maybe the question "How effective is the cognitive strategy application" can be modified to something along the lines "To what extent is the cognitive strategy application maintained and generalized … four weeks after discharge to home"
Response: Thank you. Your suggestion was a better version, and we have modified the questions according to the recommendations in point 2 and 3 (p. 3).

4. Page 6, Intervention to be studied – although it is implicit in the text, the authors could make it explicit that reference 24 (Chapparo C, Ranka J. The PRPP Intervention Course Manual, 2018.) is the manual for the intervention and that the intervention will be carried out according to this manual. Response: This is now changed to be more explicit (p. 4).

Reviewer: 2

Dr. Kerrin Watter, The University of Queensland Comments to the Author:
Review of PRPP protocol
I would like to commend your team on a very well written protocol, and an excellently structured SCED intervention. Clinically, I see the OTs in my team use the PRPP during community rehabilitation for younger adults with ABI. I am pleased to see this tool being used in a research study in this manner, and I look forward to seeing the results in the future.
My review comments below relate to the methods and analysis sections of your protocol - my queries and suggestions will help clarify certain areas for the reader.
Response: Thank you for encouraging feedback.

Setting
You provide a detailed setting of the rehabilitation services offered across the two municipalities (with different services / units available within the health centres – e.g., assessment unit, short stay unit). It is unclear whether clients are being recruited from a specific unit / area, or from all available services / units. Could this please be clarified? This will also help readers to better understand the demographics of your selected population and their phase of recovery for your study.

Response:
Thank you for this clarifying comment. Under the sub-heading 'Setting' (p. 4) we have included the age more specific, due to comments from all the reviewers: *'The vast majority of the clients are over 65 years old, and* a typical stay in both municipalities is 2-4 weeks, with the possibility of supplementing with another 2-3 weeks or more in special circumstances, such as a drop in the client's health condition or the client's home not yet sufficiently adapted to their needs.'

We also added information under 'Participants, recruitment, and inclusion criteria' (p. 4): See comment from reviewer 1 point 6.

Intervention to be studied You provide excellent detail regarding the PRPP intervention and assessment, and information on how you will address reliability and fidelity. A point to consider highlighting in your protocol is the fact that the PRPP requires clinicians to be trained and assessed as competent in the intervention and assessment methods, and this process should help support delivery of the intervention across treating therapists (in addition to the processes and SCED procedures you are undertaking).
Response: The comment is answered under Reviewer 1's point number 5. Your insightful information is implemented in the answer.

Blind rating and inter-rater reliability Please clarify the procedure for your blinded assessment and inter-rater reliability further. Are all the assessment conditions recorded and only 20% watched? Or are only 20% being recorded to be watched? Also - who is doing the recording - please clarify who records this (e.g., treating OT).
Response: To clarify this procedure, the sentence is changed to:
'To address the inter-rater reliability[30], *20% of the assessments with the PRPP stages 1 and 2 from each phase are video recorded by the treating OT or a colleague and assessed randomly by an external and blinded PRPP-trained OT*' (p. 6) .

Procedure
Your comment on randomization needs clarifying - you state that randomization to length of baseline phase (control in your design) is recommended in the RoBiNT protocol. However, you do not state whether you are actively doing this and achieving randomisation (or how), or not. From your methods, I cannot find a statement regarding randomise a client to the determined baseline (e.g., Tier 1, 2, or 3).

Response: You can read the response under reviewer 1 point 9.

**The intervention phase: **
When you state the interdisciplinary team or relatives may prompt and give cues on the PRPP intervention, how and when will this be observed (e.g., is this within treatment sessions or external to this)? And how do you plan to measure this?
Response: The clients will sometimes have included in the intervention plan simple suggestions from the OT to follow for team members/relatives untrained in the PRPP intervention. This cannot be observed or measured but the OT will note if the participant has such an intervention plan and have a dialogue with the team and note in the qualitative data collection to what extend this is done to make it transparent if they receive more 'PRPP-like' intervention than the 9 planned sessions. Response is also given under reviewer 1 point 7.

Procedure / data analysis plan
Could you please clarify (either in data collection or data analysis section) whether the PRPP data for each of the 5 activities (for each participant) will be presented and analysed separately, or is the data to be collapsed and reported overall? This was unclear to me in your procedure, and will impact analysis.
Response: Added to this sentence to clarify the procedure will be…. *'for each task'*. And for the cognitive strategies …*'the participants'* cognitive strategy application from PRPP assessment stage 2 for each participant *for all tasks collapsed* and inserted in the Cognitive Strategy Use Profile graph[38]' (p.7).

Replication / generalisation
I became confused with your plans for replication vs earlier plans for participant recruitment. In this section, it seems you will replicate the study with 3 participants from each municipality (A and B). However, earlier in the methods you state that any patient meeting criteria will be considered for inclusion (seeking 6 participants) – will this achieve the desired numbers and location for replication? Your processes will benefit from some clarification in regard to study recruitment numbers (n=6), their location (e.g., A vs B; number per location) including numbers for replication. If you plan to recruit 3 participants from each municipality, this needs to be stated earlier.
Also, you state that more systematic replication will occur according to number of admissions. Does this mean you are seeking a sample of >6?
Response: Our goal is to recruit at least 6 participants, but we will continue to recruit participant until the end of 2022, if possible, to strengthen external validity. We will try to make that less confusing by restructuring the entire chapter (p.8) into:
'To meet the SCED standard to show experimental effect in MBD[30], three direct replications across a sample of three participants are included. This experimental effect is then systematically replicated with another sample of three participants. The first pilot was included April 2021, and we will continue to recruit participants throughout the end of 2022, even if the number exceeds two full samples of six participants altogether.'

Procedural fidelity
Is the procedure checklist being developed just for the treatment sessions, or for the entire protocol? Do you plan to rate fidelity, and will this involve independent assessors also? These are points worth clarifying here.
Response: Major revisions are made in the chapter (p. 8) and further responses can be read under reviewer 1 point 5.

Lastly, please double-check your page references on the SPENT checklist – a few seem to have changed.
Response: Thank you. We will revise the references to the pages but assume the front page added by the journal to the main document in pdf may change the pages by one page all over.

Reviewer: 3
Dr. Jade Kettlewell, University of Nottingham Comments to the Author:
Thank you for inviting me to review this manuscript. The authors present a protocol for a trial to investigate the effectiveness of the Perceive, Recall, Plan and Perform System (PRPP) for

older adults with ABI. The PRPP is a standardised way of assessing and exploring how effective a patient is at applying cognitive strategies to various tasks. The authors have chosen a single case experimental design, for which a rationale is provided.

The manuscript is well written and concise considering the complexity of the proposed trial and intervention. The methods are described in a detailed and clear way to enable replication.
Response: Thank you for motivating feedback. To your comment, we will also add that the PRPP intervention are standardized as well as the PRPP assessments.

I have some minor suggestions, which I hope the authors will consider. Page numbers refer to pages in the pdf proof.

Abstract
Page 2, line 32: It would be good to have an indication of what you mean by older adults, it could simply be (i.e. over 65) or (aged 65+) etc. The definition of 'older adult' varies so it is good to give the reader an idea of the population you are investigating.
Response: This is commented by reviewer 1 and 2 as well, and you will find the answer under reviewer 1 point 6 and also under reviewer 2's comment around 'Setting'.

Page 2, line 40: You state 'persons' but it would be better if you stated 'older adults' here for consistency in population.
Response: This is connected to the answer above, and also a wish from us to present that the persons behind the client and older adults are more than these two roles.

Page 3, line 15: Expand MDBs. Response: Expanded to 'Multiple baseline designs'

Page 3, line 36-37: Consider rewording sentence as I misread the first time, suggest the following, 'It is essential (or you could use important) that these patients are both empowered and able to reach their maximum level of independence for a sustainable health service system'.
Response: Thank you for the suggestion. We follow your recommendation and change the sentence into: 'It is essential that these patients are both empowered and able to reach their maximum level of independence for a sustainable health service system[3]' (p. 1).

Page 4, line 42: 'evaluate occupational performance and train mastery...' it would be useful to have a very brief definition of 'task mastery' after this statement. You could put it in brackets before next sentence. I appreciate readers will understand what mastery means in an everyday context, but what does it mean in the context of your trial/intervention?
Response: Without adding a lot of extra words, we clarify by changing the sentence into: '…,and it functions to both evaluate occupational performance and train *independent* mastery in everyday situations[24]' (p.2).

Page 4, line 52: 'older clients', why have you changed from patients to clients? Keep it consistent. Response: The term patient is changed into client through the paper to be consistent.

Page 4, line 58: Add age range after 'older adults'. See comment about abstract.
Response: This is commented by reviewer 1 as well, and you can find the response under point 6.

Page 5, line 36-39: Is there reason for not choosing a RCT linked to limited OTs being trained in PRPP or is the reason because you wouldn't be able to identify enough patients through those OTs working in the community. This is a confusing statement as you have presented two ideas. It would be good if you could expand on this and explain why a RCT is not an option. You might have to briefly describe how patients will be identified/initial contact if it is the trained OTs that will limit your ability to recruit patients.
Response: To clarify this we have changed the sentence from:
'First, there are few PRPP-trained OTs working in community-based rehabilitation in Norway; thus, it will be difficult to get enough participants for a randomized controlled trial.' Into:

‘First, there are few PRPP-trained OTs working in community-based rehabilitation in Norway; thus, *they cannot provide the PRPP intervention for* enough participants for a randomized controlled trial’ (p. 3).

The identification of participants and recruitment process is described under the chapter ‘Participant, recruitment, and inclusion criteria’ (p. 4).

Page 6, line 7-8: Did you speak to patient representatives from the stroke association you mention, if so how many? Did you speak to any carers?
Response: We clarified this by changing the sentence from:
‘The Norwegian Association for Stroke Survivors[35] was contacted to get input on the trials’ relevance.’ Into:

‘The Norwegian Association for Stroke Survivors[35] was contacted *on* behalf of stroke survivors and their relatives to get input on the trials’ relevance’ (p.3).

Page 6, lines 24-27: font looks different here, please amend
Response: Font is changed from Calibri 11 to Calibri 12 (p. 4).

Page 6, lines 41-42: You state 'any patient admitted to a health centre with an ABI will be considered...' - are there any specific inclusion criteria? I know I have mentioned before, but it would be good to have repetition of the age criteria here as it isn't clear whether these health centres accept patients that are younger than 65 years.
Response: We have changed the text for more transparency (p. 4). Further explanation can be read under reviewer 1 point 6.

Page 6, line 48: 'more challenging tasks' please provide an example of what this would involve.
Response: To analyse activities and their demands related to a person’s abilities are one of the core expertise of occupational therapy. What is a more challenging task will depend highly on the participants (cognitive) challenges, and an example will may not show that. That is why our suggestion is not an example, but though to clarify. We add information to the sentence:

‘If the participant shows mastery above 85% of PRPP assessment stage 1, they either need to be assessed in more *cognitively* challenging tasks *based on the OTs clinical reasoning* or will be excluded with “effective cognitive strategy applications in occupational performance” (p. 4).

Page 6, line 55: As mentioned before, provide a definition of 'mastery'. You may think it is more appropriate to add this here rather than above (see previous comment).
Response: We have clarified what is meant by this term. See previous comment.

Page 7, line 26: Will you be collecting any data about 'usual care'? if so, please add information about this.
Response: We have restructured the section and added information to make this more transparent, see reviewer 1, point 7.

General comments:
1. Will you be involving any patient/service user representatives to support the running of your trial? For example, will they be involved in developing patient facing information or will they be involved in any of the analysis?
Response: There will be no other patient representative involvements other than the dialogue in the planning of the study as described under the sub-heading ‘Designing the trial’ (p. 3) as commented above.

2. How will you ensure diversity in your sample?
Response: The sample will be the actual clients admitted to these community health services with broad inclusion criteria. The first client to meet the inclusion criteria will be randomized to the actual baseline phase in line, regardless of the client is specific suitable to ensure diversity. There will not be picked special or extra clients for the samples to get a particular type of client beyond the inclusion criteria. In SCEDs we are interested in a case, and in this study the case is an individual and not a

group, and therefore it is not important with a broad spectre of diverse people to e.g., calculate the mean in a representative group.

VERSION 2 – REVIEW

REVIEWER	Manolov, Rumen University of Barcelona
REVIEW RETURNED	27-Apr-2022

GENERAL COMMENTS	I appreciate the possibility to review revised version of the manuscript entitled “Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: Protocol for a single-case experimental design with multiple baselines" submitted for publication to BMJ Open. As for the initial submission, my review will focus on methodological and statistical aspects, as I am not an expert in the substantive topic (brain injury in older adults, cognitive challenges, and community-based rehabilitation). The manuscript is greatly improved, with the authors introducing noteworthy modifications, in relation (but not limited to) the following: 1. Rewording some of the research questions. 2. Adapting some relevant wording for the data analytical plan (e.g., “experimental control” instead of “power”). 3. Adapting the wording referring to the number of measurements required per phase in SCED designs. 4. Making clearer the minimal number of participants to be recruited plus the possibility to recruit more than the minimum. 5. Providing details about the age of the participants. 6. Providing a justification regarding why a randomized controlled trial is not considered feasible. 7. Providing details about procedural fidelity. 8. Providing details about blinding. 9. Making clearer what is meant by “treatment as usual”. 10. Making clearer what is mean by “mastery”. 11. Trying to make clearer the plan about randomization. 12. Making clearer the distinction between measurements points and the number of days during which measurement takes place. 13. Making clearer the duration of the intervention phase. 14. Making clearer the expectation about generalization to a variety of everyday tasks and contexts. 15. Making clearer the expectations about the data pattern. 16. Making clearer which descriptive statistics will be used. 17. Extending the text on limitations. In terms of further aspects requiring the authors’ attention: 1. Page 2 of the revised manuscript (Page 26 of the submission PDF), Lines 25-26: the text “investigates how effective” should read “investigates how effectively” 2. Page 3 of the revised manuscript (Page 27 of the submission PDF), Les 24-27: the text “In SCED the experimental control comes from repeated measures within the individual participant” should read something like “In SCED the experimental control comes from repeated measures within the individual participant, taken under different conditions manipulated by the researcher”. 3. Page 6, Procedure: The modified sentence “The first participant included in each municipality will be assigned by the OT to the first of 3 tiers and randomized to a baseline phase of 3 days” is still not clear to me. If the first participant who enters the study goes

	necessarily to the 3-day baseline (i.e., the order of entering the study determines the baseline to which a client is assigned), I do not see the randomization element. I would more clearly see a randomization element if, for instance, when having 3 participants there is a random determination of which of them goes to the 3-day baseline, which of them goes to the 5-day baseline, and which of them goes to the 7-day baseline. According to my perspective, these three points are rather minor and do not require an additional round of review, as the small modifications required can be easily verified by the Editor. In any case, it is the Editor's decision how to proceed.

REVIEWER	Watter, Kerrin Princess Alexandra Hospital Health Service District, ABI TRS
REVIEW RETURNED	11-May-2022

GENERAL COMMENTS	Thank you for the opportunity to re-review your paper. In your revised manuscript, you have incorporated suggestions well from the reviewers and appropriately addressed many of the areas I identified in my first review. However, four small areas (relating to the methods and analysis sections of the protocol) still require some additional information, particularly around procedure and process. These are detailed below. **Blind rating and inter-rater reliability** Thank you for providing additional detail on the blinded assessment process (see page 7, lines 42 – 46), however additional detail is required regarding the process of video taping and selection. - Please specify which 20% of sessions are chosen to be videoed, and the process to determine this / how this was determined (e.g., randomised session numbers vs planned sessions). Or, are you videoing all sessions and then choosing to rate 20% of these? If so, how are you determining which 20% will be watched? **Procedure - randomization** I still have concerns about your presentation of 'randomisation' in this section. From your description, it appears you are allocating clients consecutively to the different tiers (and baseline lengths) of the program - i.e., participant 1 = tier 1, participant 2 = tier 2, etc.. This is not random allocation. An example of random allocation would be your first client being randomly allocated to any of the three tiers. **The intervention phase:** Line 36-39: You state: "To what degree the interdisciplinary team or relatives give prompts and cues based on the PRPP intervention will vary and be described." This process still needs to be clarified. Please specify how you will identify that relatives and team members are giving prompts and cues. **Procedural fidelity** Thankyou for providing additional information on the checklist, however additional information on this process is required. Please specify the number / amount of sessions that the treating OT will complete the checklist for (e.g., is this 100% of sessions?). What is the process of how and when the first author will assess the checklist – this is not clear. E.g., is this during the treatment session? From a video recording of the session?

	And will the first author assess 100% of all sessions across all participants? Please specify this. I look forward to receiving the next version of your paper for review, and wish you all the best in this research.

REVIEWER	Kettlewell, Jade University of Nottingham, Centre for Health Innovation, Leadership & Learning
REVIEW RETURNED	19-May-2022

GENERAL COMMENTS	Much improved manuscript, thank you for addressing comments from the previous review. I have no further comments on this version and feel it is suitable for publication.

VERSION 2 – AUTHOR RESPONSE

Reviewer: 1
Dr. Rumen Manolov, University of Barcelona Comments to the Author:
I appreciate the possibility to review revised version of the manuscript entitled "Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: Protocol for a single-case experimental design with multiple baselines" submitted for publication to BMJ Open.
As for the initial submission, my review will focus on methodological and statistical aspects, as I am not an expert in the substantive topic (brain injury in older adults, cognitive challenges, and community-based rehabilitation).
The manuscript is greatly improved, with the authors introducing noteworthy modifications, in relation (but not limited to) the following:
1. Rewording some of the research questions.
2. Adapting some relevant wording for the data analytical plan (e.g., "experimental control" instead of "power").
3. Adapting the wording referring to the number of measurements required per phase in SCED designs.
4. Making clearer the minimal number of participants to be recruited plus the possibility to recruit more than the minimum.
5. Providing details about the age of the participants.
6. Providing a justification regarding why a randomized controlled trial is not considered feasible.
7. Providing details about procedural fidelity.
8. Providing details about blinding.
9. Making clearer what is meant by "treatment as usual".
10. Making clearer what is mean by "mastery".
11. Trying to make clearer the plan about randomization.
12. Making clearer the distinction between measurements points and the number of days during which measurement takes place.
13. Making clearer the duration of the intervention phase.
14. Making clearer the expectation about generalization to a variety of everyday tasks and contexts.
15. Making clearer the expectations about the data pattern.
16. Making clearer which descriptive statistics will be used.
17. Extending the text on limitations.

Response: Thank you for encouraging comments and further, for the insightful reviews and recommended changes.

In terms of further aspects requiring the authors' attention:

1. Page 2 of the revised manuscript (Page 26 of the submission PDF), Lines 25-26: the text "investigates how effective" should read "investigates how effectively"

Response: Changed according to suggestion.

2. Page 3 of the revised manuscript (Page 27 of the submission PDF), Les 24-27: the text "In SCED the experimental control comes from repeated measures within the individual participant" should read something like "In SCED the experimental control comes from repeated measures within the individual participant, taken under different conditions manipulated by the researcher".

Response: Changed according to suggestion.

3. Page 6, Procedure: The modified sentence "The first participant included in each municipality will be assigned by the OT to the first of 3 tiers and randomized to a baseline phase of 3 days" is still not clear to me. If the first participant who enters the study goes necessarily to the 3-day baseline (i.e., the order of entering the study determines the baseline to which a client is assigned), I do not see the randomization element. I would more clearly see a randomization element if, for instance, when having 3 participants there is a random determination of which of them goes to the 3-day baseline, which of them goes to the 5-day baseline, and which of them goes to the 7-day baseline.

Response for both reviewer 1 and 2 about: The way we see it is that the randomization element is that no one knows which participant is next to be admitted to the health centers with an ABI, and they go into a predefined baseline phase that is next in line in the order 3, 5 or 7 days. That means the length of the baseline is not selected based on type of participant, but a random determination of which participant goes in to the 3-day baseline, the 5-day baseline and to the 7-day baseline. This secures that we have a participant in all three tiers. It also means that the whether the researchers or the occupational therapists have influence who are offered rehabilitation services and that the occupational therapists that include the participants after the inclusion criteria give the participant the next-in-line baseline phase. We can see your point that this not meet the criteria for the definition of randomization, and we will modify the sentences. At the same time, the way we organize the 'randomization' can be defended in line with Tate & Perdices (2019, p.128): In non-concurrent MBD the length of the baseline phases in each tier are predefined, and then as participants are recruited, they are randomly assigned to a particular tier.

Tate RL, Perdices M. Single-Case Experimental Designs for Clinical Research and Neurorehabilitation Settings. Planning, Conduct, Analysis and Reporting. New York: Routledge 2019.

According to my perspective, these three points are rather minor and do not require an additional round of review, as the small modifications required can be easily verified by the Editor. In any case, it is the Editor's decision how to proceed.

Reviewer: 2
Dr. Kerrin Watter, Princess Alexandra Hospital Health Service District Comments to the Author:
Thank you for the opportunity to re-review your paper. In your revised manuscript, you have incorporated suggestions well from the reviewers and appropriately addressed many of the areas I identified in my first review. However, four small areas (relating to the methods and analysis sections of the protocol) still require some additional information, particularly around procedure and process. These are detailed below.

Response: Thank you for your insightful reviews that help our manuscript to improve and to be more transparent for readers.

<b>

Blind rating and inter-rater reliability Thank you for providing additional detail on the blinded assessment process (see page 7, lines 42 – 46), however additional detail is required regarding the process of video taping and selection.
- Please specify which 20% of sessions are chosen to be videoed, and the process to determine this / how this was determined (e.g., randomised session numbers vs planned sessions). Or, are you videoing all sessions and then choosing to rate 20% of these? If so, how are you determining which 20% will be watched?
****
Response: The section is changed to make this more transparent.

Procedure - randomization
I still have concerns about your presentation of 'randomisation' in this section. From your description, it appears you are allocating clients consecutively to the different tiers (and baseline lengths) of the program - i.e., participant 1 = tier 1, participant 2 = tier 2, etc.. This is not random allocation. An example of random allocation would be your first client being randomly allocated to any of the three tiers.
****
Response: See comments under reviewer 1.

**The intervention phase: **
Line 36-39: You state: "To what degree the interdisciplinary team or relatives give prompts and cues based on the PRPP intervention will vary and be described."
This process still needs to be clarified. Please specify how you will identify that relatives and team members are giving prompts and cues.

Response: The interdisciplinary team will only give prompts and cues if the OTs actively supervise them to do so, and in that way the OT will have insight into who gives prompts and cues based on the PRPP. The sentence is changed to clarify this.

Procedural fidelity
Thank you for providing additional information on the checklist, however additional information on this process is required.
Please specify the number / amount of sessions that the treating OT will complete the checklist for (e.g., is this 100% of sessions?).
What is the process of how and when the first author will assess the checklist – this is not clear. E.g., is this during the treatment session? From a video recording of the session?
And will the first author assess 100% of all sessions across all participants? Please specify this.

Response: Only the research procedures are assessed with a checklist and not the single treatment sessions, others than that they are completed, and minutes used each time. It is specified why the dynamic and individualized treatment sessions are not assessed with a checklist. We have specified that the treating OT complete all the steps in the procedure checklist for all the participants to make this more transparent.

I look forward to receiving the next version of your paper for review, and wish you all the best in this research.

Reviewer: 3
Dr. Jade Kettlewell, University of Nottingham Comments to the Author:
Much improved manuscript, thank you for addressing comments from the previous review. I have no further comments on this version and feel it is suitable for publication.
Response: Thank you

VERSION 3 – REVIEW

REVIEWER	Manolov, Rumen University of Barcelona
REVIEW RETURNED	26-Jul-2022

GENERAL COMMENTS	I appreciate the possibility to review the newly revised version of the manuscript entitled “Effectiveness of the Perceive, Recall, Plan and Perform intervention for persons with brain injury in community-based rehabilitation: Protocol for a single-case experimental design with multiple baselines" submitted for publication to BMJ Open. As for the initial submission, my review will focus on methodological and statistical aspects, as I am not an expert in the substantive topic (brain injury in older adults, cognitive challenges, and community-based rehabilitation). The manuscript is improved, according to the comments made by the reviewers and is ready for publication. The only relevant point that I will address refers, again, to randomization. I do understand that the authors follow Tate and Perdices (“In nonconcurrent MBD the length of the baseline phases in each tier are predefined, and then as participants are recruited, they are randomly assigned to a particular tier.”). I also understand that neither the researchers nor the occupational therapists know in advance which participant will be assigned to which baseline. However, I do not think that the procedure followed is an actual randomization. On the one hand, following the citation, “as participants are recruited, they are” automatically (not randomly” assigned to a particular trial (i.e., the shortest baseline). On the other hand, a real randomization would be to plan for 3 participants, and then to decide for the first participant entering the study whether the baseline would be 3, 5, or 7 sessions long. This would be an actual random element. What the authors are doing could be called “haphazard” or “accidental”. Consider the similarity with sampling. An actual random sample requires a list of all participants and using random number generators to decide which participants take part in a study. In contrast, if the sample consists of the people that happen to enter the hospital during a given month, the researchers and the occupational therapist would not know which this people are (i.e., their identities) before they enter the hospital. This would appear to be random due to the lack of a priori certainty. However, this would be a “convenience” sample (it is also called “accidental”, because it appears to happen “by accident”) and not a random sample (because it is not possible for all participants in the population, which has to be listed, to take part in the study). Analogously, for the participants in the study described in the protocol, the one who happens to enter first, does not have the possibility to be assigned to longer baselines.