PEER REVIEW HISTORY

ARTICLE DETAILS

TITLE (PROVISIONAL)	Effect of adjusting the challenge–skill balance for occupational therapy: study protocol for a randomized controlled trial
AUTHORS	Yoshida, Ippei; Hirao, Kazuki; Kobayashi, Ryuji

VERSION 1 – REVIEW

REVIEWER	Stefania Costi University of Modena and Reggio Emilia, and Local Health Authority IRCCS of Reggio Emilia, Italy
REVIEW RETURNED	11-Jun-2018

GENERAL COMMENTS	Dear Authors of the Manuscript "Study protocol: Adjusting the challenge -skill balance for occupational therapy in a recovery rehabilitation unit: A proposal for a randomized controlled trial". I found the study protocol interesting and addressing and important topic for occupational Therapy. However, I ask you to do some minor revision before the manuscript can be published on BMJ open. - The reviewer provided a marked copy with additional comments. Please contact the publisher for full details.

REVIEWER	Dr. Afsoon Hassani Mehraban Iran University of Medical Sciences, School of Rehabilitation Sciences, Occupational Therapy Department, Tehran, Iran
REVIEW RETURNED	19-Aug-2018

GENERAL COMMENTS	This study presented one of the important concern in occupational therapy practice with sound methodology, but there are some points as follows: 1- Introduction: you can add some explanation about meaningfulness of activity in this section that can help you to interpret and justify your work. 2- Randomization: Is there any possibility of contamination of two groups? If yes how you control this confounder? 3- Experimental group: a)Are you using any component based, compensatory approach techniques in intervention and control groups? If yes please mention it, and if no I think you need to add it because you have an outcome measure (Clinical global impression) for showing the impact of treatment. Also, if you donot consider this issue, it can cause ethical concerns for your patients and you will limit their comprehensive therapy.

	b) in stage 4 you need to clarify the therapist's role for example "by using activity analysis principles ..... 4- Outcomes: Evaluation in implementation status for occupational therapy: Please provide more information and references. 5- Study limitations: this section needs to be re-write for example the first mentioned point is not limitation it is just outcome measure selection process. 6- conclusions: must be deleted. 7- I recommend to read the article: Boutron I, Altman DG, Moher D, Schulz KF, Ravaud P; CONSORT NPT Group. CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. Ann Intern Med. 2017;167(1):40-47. PMID: 28630973 and complete any gap in your article ,Also you can update your references with articles about meaningfulness of activity.

VERSION 1 – AUTHOR RESPONSE

RESPONSE TO REVIEWER 1:

We wish to express our appreciation to the Reviewer for his or her insightful comments, which have helped us significantly improve the paper.

Reviewer number: 1	Responses
Please state any competing interests or state 'None declared':	We stated 'None declared'.

p4 l36: I find this paragraph difficult to understand. Please, remove redundancy and re-write a concise and straightforward sentence.	We corrected this paragraph to make it easy to understand. [Pre] Several research reports have analyzed the relationship between the flow model and health-related quality of life (QOL) [17-21]. In our research using the flow model, we analyzed activities supported by occupational therapy for the elderly using an adult day program, and showed that there was a difference in recognition [7]. In other words, even within conventional client-centered occupational therapy, there is a difference in recognition from the viewpoint of challenge and ability. Therefore, we believed that more effective occupational therapy could be provided by adjusting these, and invented a new process called adjusting the challenge-skill balance for occupational therapy (ACS-OT). [Post] Several cross-sectional studies using the flow model have been reported [19-23]. In our previous research using the flow model to shape the OT practice, although the occupational therapist judged the activity to be suitable for the clients, clients themselves felt that the activity made them feel anxious, bored, and apathetic [9]. We believe that more effective OT and realization of meaningful activities for clients could be provided by adjusting the challenge–skill balance. Therefore, we invented a new process called adjusting the challenge–skill balance for OT (ACS-OT).
p4 l51: I would like you to explain more clearly why there is the necessity to do this new trial. It is written later on in the manuscript, but it should be clear at this stage.	We added contents about the necessity of this verification. [Pre] To generalize the results of this research to various fields, it is necessary to develop research in this area. [Post] However, this previous research only tested one activity, which limits the generalization of the effect of ACS-OT on the larger population and to different activities. Therefore, we propose to examine the effect of ACS-OT on clients in the recovery phase who need timely support on activities of daily living (ADL) and occupational performance necessary to return to their home life.
p5 l8: Why did you choose to exlude adult patient under 50 years? Please, provide evidence or motivation.	We corrected the description to include reasons for exclusion criteria. [Pre]

	Clients 50–99 years old admitted to the recovery rehabilitation unit will be eligible for this study. [Post] To minimize heterogeneity of the client sample, we will test clients aged 50–99 years old admitted to the recovery rehabilitation unit. This age range was chosen as the average age of patients admitted is 76.8 ± 12.7 years, and we extended the target age range to ± 2 standard deviations.
p5 l12: I was wondering why you did not mentioned the average number of OT treatments on both groups, or the duration of hospitalization in the rehabilitation ward. The "quantity" of OT treatment in both groups is a topic that should be addressed in the methods, otherwise it should be included in the limits of the protocol.	We added a statement on the indication of the number of OT treatments in both groups. [Post] The average admission period in this unit is 8–10 weeks for cerebrovascular disease and 6–8 weeks for musculoskeletal disease. The intervention period in this study is set to 6–10 weeks, and the number of interventions would be 36–60.
p6 l36: I ask you to provide motivation for the inclusion of patients with different pathologies in your sample. I suggest you to justify this choice in the introduction. It might also be appropriate to cite You could also cite Schiavi M et al, PMID: 28264614	Thank you for reporting a suitable review. As in the review, this research is also a client-centered occupational therapy practice, focusing on ADL and occupational performance. In order to show that it is a process that can be used in various diseases, we targeted cerebrovascular / exercise machines, which are the major diseases in recovery rehabilitation units. It was added to the first paragraph of the method. [Post] As discussed in a previous review [25], this study represents the practice of client-centered OT, focusing on ADL and occupational performance. To determine if ACS-OT could be effective with various diseases, we targeted cerebrovascular and musculoskeletal disease, which are the main diseases observed at our recovery rehabilitation unit.
p6 l45: Please, declare that allocation process is "concealed" somewhere in this paragraph.	We added a description about Conceal. [Pre] The statistician will create a block random pattern for each layer, and will notify the occupational therapists of the assignment result.

	[Post] Our statistician will create a block random pattern of each layer, but the grouping will be single-blinded. On the basis of the calculated random pattern, the assignment will be known to the occupational therapist.
p7 l28: Is it possible to estimente for how may weeks, on average, for both groups?	We referred to past hospitalization data, and described the expected period. [Post] The average admission period in this unit is 8–10 weeks for cerebrovascular disease and 6–8 weeks for musculoskeletal disease.
p7 l48: What does it mean? I do not understand why the size of the location could influence the perceived difficulty.	It was meant that the distance to move and the range of activity affected the challenge level (difficulty). We have modified so that it will be understood. [Pre] size of the location in which the activity occurs [Post] movement range required for activity
p8 l24: Please, put the outcome measures in the order you listed them at page 5, lines 12-15.	We fixed the description order of outcomes.
p8 l36: Provide a reference as you did for the other assessment instruments.	We added a reference about EQ-5D.
p8 l46: why are you decalring that reliability and validity has been confirmed for this measure only? I would cut this sentence, or introduce this information for all the measures you rely on in this protocol.	Since details on reliability and validity are stated in the references, we unified them as undescribed.
p10 l30: I find this first part of the Discussion redundant. Please, summarize the key concepts.	We modified (deleted) it to be a description centered on the advantages of ACS-OT. [Pre] This research protocol has been prepared to examine the effect of adjusting the challenge-skill balance process in occupational therapy on subjective QOL of clients in a recovery rehabilitation unit, using an RCT. The main purpose of occupational therapy is to make it possible for clients to participate in the activities of daily life that they

	desire. To achieve this, practical models such as the Canadian Model of Occupational Performance [40] and Model of Human Occupation [41] are advocated. On the other hand, Maitra [6] conducted a questionnaire survey and reported that there was a difference in perception between the occupational therapist and the client, even though it seemed that the therapist had provided client-centered occupational therapy. Thus, it is necessary to facilitate the sharing of the meaning of "occupation" between the therapist and the client, in order to understand and support the client's desired activities. The process used in this study was devised based on the flow model and shares perception of the activities between client and occupational therapist, as well as highlighting the importance of the provision of appropriate activities for clients. The client's perception of their challenge-skill balance is highly relevant to the degree of difficulty and occupational performance of activities provided by occupational therapy. We believe that understanding the client's subjective assessment of their activities, according to their challenge-skill balance, supports the provision of effective occupational therapy. This study has been designed as an RCT. To verify the effect on this occupational therapy process, we believe that this research design is necessary to more clearly show the effect of the intervention. In addition, we aim to homogenize the two groups by stratified blocking using disease and subjective health. We have not set strict age limits as inclusion criteria, as this process is assumed to be adaptable to clients of a wide range of ages. [Post] This research protocol proposal was prepared to examine the effect of ACS-OT on subjective QOL of clients in a recovery rehabilitation unit as an RCT. The process to be used in this study was devised based on the flow model and shares the perception of activities between the client and occupational therapist. Also, this process highlights the importance of provision of appropriate activities for clients. The client's perception of their challenge–skill balance is highly relevant to the degree of difficulty and occupational performance of activities provided by OT. We believe that understanding the client's subjective assessment of their activities according to their challenge–skill balance supports effective OT. A previous RCT that used a similar protocol for older adults in an adult day program observed improvements in health-related QOL [24]. However, only one activity was examined and a follow-up period was not set. The current proposal will cover several activities such as toilet, bathing, cooking, shopping in which clients would require assistance during admission to a recovery rehabilitation

	unit. Furthermore, by setting a follow-up period, we will verify the continuity of the effect in addition to the direct effect of ACS-OT implementation. We hypothesize that ACS-OT will enhance the effects of positive emotions and self-affirmation by facilitating activities suitable for clients. As such, subjective QOL (according to the Ikigai-9) is the main outcome. Importantly, this suggests that improvements in OT yield new findings on subjective QOL. In addition, using a GLMM, it will be possible to perform an analysis that considers individual differences as a random effect.

RESPONSE TO REVIEWER 2:

We wish to express our appreciation to the Reviewer for his or her insightful comments, which have helped us significantly improve the paper.

Reviewer number: 2	Responses
Please state any competing interests or state 'None declared':	We stated 'None declared'.
1- Introduction: you can add some explanation about meaningfulness of activity in this section that can help you to interpret and justify your work.	We corrected this paragraph to make it easy to understand. [Pre] In many countries, client-centered practices are the basis for occupational therapy [1-5]. [Post] In many countries, client-centered practice is the basis for OT; this practice contributes to the realization of meaningful activities for the client [1-5], which are defined as familiar activities which aligns with an individual's pursuit of valued developmental goals to maintain a personally meaningful lifestyle [6-7].
2- Randomization: Is there any possibility of contamination of two groups? If yes how you control this confounder?	We added that there was almost no possibility of contamination of two groups. [Post] We intend to individually randomize patients in this research, and we use a dedicated process support application in the experimental group, but not in the control

	group. Therefore, there is almost no possibility of contamination between the two groups.
3- Experimental group: a) Are you using any component based, compensatory approach techniques in intervention and control groups? If yes please mention it, and if no I think you need to add it because you have an outcome measure for showing the impact of treatment. Also, if you do not consider this issue, it can cause ethical concerns for your patients and you will limit their comprehensive therapy. b) in stage 4 you need to clarify the therapist's role for example "by using activity analysis principles	a) The compensatory approach in occupational therapy is used in both groups, and we added about the method concerning this in the experimental group. [Post] In the experimental group, the compensation approach, such as environmental adjustment and use of technical aid, will be used for adjusting the challenge level. b) We clearly indicated the role of occupational therapist in stage 4. [Pre] Based on these components, adjustments to the challenge-skill balance of the activities will occur. [Post] Based on these components and traditional assessment and activity analysis, the occupational therapist will reconfigure the activity contents after adjusting the challenge–skill balance.
4- Outcomes: Evaluation in implementation status for occupational therapy: Please provide more information and references.	Since this evaluation method was prepared for this research, there is no reference. Therefore, we added details. [Pre] This evaluation is rated on a seven-point scale and consists of the following three items: 1. Ability to identify the difference in recognition between the client and the therapist; 2) Whether the differences in recognition between the client and the therapist were adjusted during occupational therapy; 3) Whether occupational therapy suitable for the client was provided. [Post] This evaluation method was prepared for this research to verify whether the experimental process is feasible. This evaluation is rated on a seven-point scale from “very poor”

	(1) to “excellent” (7) and consists of the following three items: 1) Whether differences in recognition between the client and the therapist were confirmed, 2) whether differences in recognition between the client and the therapist were adjusted during OT, and 3) whether OT suitable for the client was provided. The occupational therapist will fill out this evaluation following each interventional session with a client.
5- Study limitations: this section needs to be re-write for example the first mentioned point is not limitation it is just outcome measure selection process	After deleting part of the limitation, I added the blind problem. [Pre] Subjective evaluations such as subjective QOL, health-related QOL, and flow experience is highly likely to result in measurement bias. With regard to this point, we will devise measures to reduce this bias as much as possible, by adopting an RCT design and carrying out self-assessed outcome measurements. In addition, there is a blind problem in RCT. The implementers in this study are occupational therapists, it will be difficult to blind occupational therapist for assignment and intervention method. We will use a convenience sample from the recovery rehabilitation unit of a single hospital, which may not be representative of all clients in a recovery rehabilitation unit. This study will not include acute patients, subacute patients, outpatients, and clients who use community rehabilitation services. Therefore, our results will not be able to be generalized to these populations. In view of these limitations, we will comply with the protocol and show the effect of adjusting the challenge-skill balance process. [Post] Subjective evaluations, such as subjective QOL, health-related QOL, and flow experience, are highly likely to result in measurement bias. To address this, we will adopt an RCT design and perform self-assessed outcome measurements. In addition, there is a blinding problem in this RCT as the investigators in this study are occupational therapists, and thus, it will be difficult to blind occupational therapists to their assignment and intervention method. We will use a convenience sample from the recovery rehabilitation unit of a single hospital, which may not be representative of all clients in a recovery rehabilitation unit. This study will not include patients with acute or subacute diseases, outpatients, and clients who use community

	rehabilitation services. Therefore, our results cannot be generalized to these populations.
6- conclusions: must be deleted.	We deleted the conclusion.
7- I recommend to read the article: CONSORT Statement for Randomized Trials of Nonpharmacologic Treatments: A 2017 Update and a CONSORT Extension for Nonpharmacologic Trial Abstracts. and complete any gap in your article, Also you can update your references with articles about meaningfulness of activity.	We revised the manuscript with reference to SPIRIT statement and added explanation about the meaning of occupation to the background.
Required amendments will be listed here; please include these changes in your revised version: 1.Patient and Public Involvement statement We have implemented an additional requirement to all articles to include 'Patient and Public Involvement statement' within the main text of your main document.	We added **Patient and Public Involvement statement**. [Post] All recruited clients will need to provide written, informed consent. The clients will be not involved in the recruitment to and conduct of this study. We have designed the study to minimize client time and physical restrictions; all participants are free to withdraw from the study at any time. Structural evaluation on client's burden in RCTs will be not performed. We will inform the results to the applicants.