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Brain Impairment

Supplementary Material

Addressing unmet needs following minor stroke (SUN study): a randomised controlled trial

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Appendix 1

As Treated (AT) analysis

To check the robustness of the ITT analysis, an As Treated (AT) analysis was also conducted. Thirteen participants who were assigned to the intervention group in the ITT analyses subsequently declined the intervention (and thus were re-allocated to the control group for the AT analysis as they therefore received usual care at the hospital rather than the intervention). These participants were included in the ITT analysis; however, we sought to compare the ITT with actual treatment received by the whole group to assess for any unexpected findings due to their drop out from their allotted intervention in order to check the robustness of the analysis. This second analysis formed the basis of the AT analysis. Performance on one baseline variable (SF-36 physical functioning) predicted whether participants moved from the intervention group in the ITT analysis to the control group in the AT analysis. Specifically, participants with higher physical functioning at baseline on the SF-36 were more likely to participate in the intervention activities and were therefore less likely to be moved from the intervention group to the control group during the AT analyses, $t(32)=-2.29$, $p=.029$.

SUNSU

For unmet need on the SUNSU, the AT results replicated the ITT results. Specifically, the addition of trial condition to the SUNSU unmet need model did not significantly improve the model, $\chi^2(3)=3.10$, $p=.377$. Neither the main effect of trial condition, $t(159.75)=-0.23$, $p=.818$, nor the interaction effect, $\chi^2(2)=1.83$, $p=.400$, were significant.. In terms of SUNSU support received, there was no significant interaction or change over time ($p > .05$).. The AT analysis replicated the interaction between time and condition for ongoing need for support on the SUNSU (SUNSU support continue), with the time x condition interaction becoming marginally significant, $t(109)=1.92$, $p=.057$. This difference was such that control group reported a growing need for support to continue into the future, while the intervention group experienced a decrease in the reported need for help

such that they required somewhat less help at T3, t(161)=1.85, p = .066 (however this difference was only marginally significant).

MPAI-4

For MPAI-4 full scale and all three subtest scores (ability, adjustment, and participation), the AT analyses replicated the ITT analyses with both groups improving over time, p<.001$MPAI_{total}$, p = .007 $MPAI\text{-}4_{ability}$, p = .001 $MPAI\text{-}4_{adjustment}$; p < .001 $MPAI\text{-}4_{participation}$), without a significant differences or meaningful trends between conditions (all p > .05).

EXITS

For the EXITS Now (current group memberships) in the AT analysis, the control group became increasingly isolated at each timepoint (however the change was marginally significant, $t(105)=-1.84$, $p = .0685$), while the intervention group showed an attenuated decline in their social connectedness, $t(100) = -.047$, $p = .637$. However, as the overall interaction was non-significant, $\chi^2(2) = -.63$, p = .730, the finding should be interpreted with caution. For the EXITs continuation of groups (EXITS Continue), there was no significant differences between groups in the perception that one's social groups were sustained from pre-stroke, no consistent trend over time, and no difference in the trend over time (all p > .05). For the EXITS new groups (EXITS New), there were no significant differences between the two groups according to the degree to which participants felt they had joined new social groups since their stroke, no consistent trend over time, and no difference in the trend over time (all p > .05).

SF-36

For SF mental health the interaction between time and condition that was significant in the ITT analysis (such that people in the active group experienced a significant improvement in their mental health over time while people in control experienced no change) was non-significant in the AT analysis (p=.24). The significant improvement in the ITT analysis in SF energy with a main effect for time for both groups was similar, although the improvement in the intervention group was slightly attenuated (p = .092). For SF pain, as per the ITT analysis, no effects were significant (all p >

.05). For SF social functioning, the greater baseline social functioning in the control group at baseline, was not significant in the AT analysis ($p > .05$).

CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	1
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	1
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	2-4
	2b	Specific objectives or hypotheses	5
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	5
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	21
Participants	4a	Eligibility criteria for participants	6
	4b	Settings and locations where the data were collected	6-8
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	7-9
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	9-12
	6b	Any changes to trial outcomes after the trial commenced, with reasons	N/A
Sample size	7a	How sample size was determined	6, protocol
	7b	When applicable, explanation of any interim analyses and stopping guidelines	N/A
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	12
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	12
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	12
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	12
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those	12

		assessing outcomes) and how	
	11b	If relevant, description of the similarity of interventions	6-9
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	12-13
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	12-13
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	Fig 1
	13b	For each group, losses and exclusions after randomisation, together with reasons	Fig 1
Recruitment	14a	Dates defining the periods of recruitment and follow-up	12
	14b	Why the trial ended or was stopped	12
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	Table 1
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	13-19
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	13-19, Fig 3
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	N/A
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	13-19, Appendix
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	17
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	23-24
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	24
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	19-24
Other information			
Registration	23	Registration number and name of trial registry	25
Protocol	24	Where the full trial protocol can be accessed, if available	5
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	25

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.