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Format: Oral presentation

Blinding participants and assessors in a feasibility randomised controlled trial of peer-befriending for people with aphasia post-stroke

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Background and aims: In behavioural interventions, blinding participants to intervention versus control conditions is problematic, as is blinding assessors to participants' group allocation. When participants are provided with information about the intervention to be tested, they will know whether they are in the intervention or the control arm of the study. This is particularly problematic in psychological interventions where people who may already be distressed or anxious are likely to become even more distressed when they realise they are in the control arm of a study. To minimise potential threats to validity and maintain lack of bias, we took a number of steps in the Supporting wellbeing through PEer Befriending (SUPERB) feasibility trial for people with aphasia to ensure blinding. This presentation will report on these steps and evaluate their effectiveness.

Methods: SUPERB is a single blind, mixed methods, parallel group phase II randomised controlled trial (RCT) comparing usual care+peer-befriending (n=30) vs. usual care (n=30), starting at discharge from hospital. Little is known about what usual care for psychological support after stroke-aphasia constitutes and this study will document the services participants receive in their area for both groups. A modified 2-stage consent design has been adopted (Campbell, Peters, Grant, Quilty, & Dieppe, 2005; Torgerson & Roland, 1998), as highlighted in the Medical Research Council (MRC) framework for complex interventions (Craig, Dieppe, Macintyre, Michie, Mazareth, & Petticrew, 2008). In the first stage, all participants consent to take part in a study on adjustment post-stroke and have their data collected at three time points (i.e. baseline, 4 months, and 10 months). They know they may be compared to other people in the study receiving different packages of care, but are blind to the fact that the study tests a specific intervention (peer-befriending). Following baseline assessments, participants are randomised to either usual care+peer-befriending or usual care. At this point, a second stage consent to take part in the intervention is completed with those participants allocated to the peer-befriending arm. Rate of consent at both stages is monitored. Blinded researchers (assessors) complete assessments for both groups at 4 months and 10 months. Strategies to maintain blinding of assessors include use of scripts during assessments, asking participants not to reveal what care they have received; un-blinded researcher organising post-randomisation appointments, so that assessors cannot become unblinded by partners/carers of people with aphasia revealing information; and management of the work environment (separate

office space, different telephones, no physical or electronic access to sensitive data). Instances of un-blinding are recorded.

Results: The trial is currently underway. 38 of 60 participants have been recruited and 27 have been randomised. The 2-stage consent process has been largely successful. No instances of un-blinding by participants or researchers have been recorded. Near misses (n=4) have been recorded for the blinded researchers. These are unrelated to the assessments with participants but rather workplace factors e.g. use of email, shared calendars, overhearing telephone conversations.

Conclusions: Blinding of participants and researchers is critical to the success of a RCT. This paper raises and discusses a range of processes including a modified two stage consent process, careful preparation and monitoring of participants, researchers and workplace factors, which are all important steps to reducing the possibility of un-blinding.

References

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