

## ORCA - Online Research @ Cardiff

This is an Open Access document downloaded from ORCA, Cardiff University's institutional repository:https://orca.cardiff.ac.uk/id/eprint/130424/

This is the author's version of a work that was submitted to / accepted for publication.

Citation for final published version:

Bailey, Sarah, Boivin, Jacky, Ting, Cheong, Bailey, Christopher, Kitson-Reynolds, Ellen and Macklon, Nick 2020. Effective support following recurrent pregnancy loss: A randomized controlled feasibility and acceptability study. Reproductive BioMedicine Online 40 (5), pp. 729-742. 10.1016/j.rbmo.2020.01.022

Publishers page: http://doi.org/10.1016/j.rbmo.2020.01.022

## Please note:

Changes made as a result of publishing processes such as copy-editing, formatting and page numbers may not be reflected in this version. For the definitive version of this publication, please refer to the published source. You are advised to consult the publisher's version if you wish to cite this paper.

This version is being made available in accordance with publisher policies. See <a href="http://orca.cf.ac.uk/policies.html">http://orca.cf.ac.uk/policies.html</a> for usage policies. Copyright and moral rights for publications made available in ORCA are retained by the copyright holders.



Methodological issues	Findings	Evidence
Were women with recurrent miscarriage willing to participate in research?	Recurrent miscarriage patients showed a positive mental attitude to participating in this research	Women reported they were altruistic, keen and willing to take part in research that would help other women, even if it did not help them personally
2. What factors influenced eligibility and what proportion of those approached were eligible?	Ineligibility to participate was mainly due to the fact that the patient was already pregnant, receiving fertility treatment or already participating in another research study	126 potential participants were screened for eligibility. 107 of these were eligible
3. Was recruitment successful?	Recruitment in Site A successful, but fell below expectations in Site B	Total of 75 participants recruited (67 in Site A, 8 in Site B)
4. Did eligible participants consent?	Good conversion from eligibility to consent	Only 6 women declined invitation to participate in study. Main reason for lack of conversion was loss of contact between giving study information and participants confirming they wished to participate
5. Were participants willing to be randomised to control or intervention group and did they find the randomisation process acceptable?	Participants found the concept and process of randomisation acceptable.	Combined randomisation rate for both sites 62.6%. The fact that this study included an element of randomisation did not affect the participants' willingness to take part in the research
6. Were participants successfully randomised and did randomisation yield equality in groups?	Randomisation processes worked very well	Equal sized groups. Well balanced stratification. Study highlighted need to consider the number of study participants it would be necessary to recruit in order to achieve an adequate randomisation rate - suggest should include a recruitment target that is at least twice the randomisation target.
7. Did participant's use the intervention	Good adherence to overall use of PRCI, but frequency and mode of use differed to specific intervention recommendations	Participants reported consistent but varying use of the PRCI on the WRK questionnaire. Participants adapted PRCI use to suit their individual needs
8. Was the intervention acceptable to the participants?	Participants demonstrated a positive mental attitude to using the PRCI	Only one participant withdrew after randomisation to intervention. Participants reported they found the PRCI an acceptable, practical intervention to use during the stressful waiting period of a new pregnancy

Methodological issues	Findings	Evidence
9. Were study data collection questionnaires completed?	There were excellent completion rates of all questionnaires. Participants reported they were happy with returning questionnaires by post	Only 4 randomised participants (out of 47) did not return questionnaires
10. Were the questionnaires understandable to the participants?	Participants showed good understanding of the pre-intervention demographic questionnaire and the HADS and these were completed accurately. Issues were raised on the use of the WRK	Pre-intervention demographic questionnaire and HADS completed accurately and in full. The study highlighted issues with the rating scale on the WRK (did not allow for the scoring of positive emotions) and confusion over whether a blank score box equated to a zero score or missing data
11. Did the questionnaires provide the researchers with the data they required?	Data generated by the study questionnaires were appropriate and valuable. However, limited data were generated that specifically assessed coping and coping strategies	Because of the lack of data generated by the questionnaires which specifically assessed coping, it was not possible to fully assess the effect of the PRCI on coping mechanisms and strategies
12. Was study retention good?	Retention rates good	Out of the 47 randomised participants, 42 completed the study
13. Were the logistics of running a multicentre study assessed?	Varying recruitment rates in two study sites	Differing recruitment success in Site A and B highlighted issues around recruitment barriers in different sites which would need consideration in future definitive study
14. Did all the components of the protocol work together?	Protocol components had excellent synergy	No difficulties were identified in the various research processes employed in this study or in the researcher's ability to implement them. For example, following recruitment, the randomisation process worked well and the participant's care moved forward to the appropriate trial arm

Table 2: Key feasibility findings (based on Shandyinde et al 2011 and Bugge et al 2013)