

Fidelity in intervention delivery

A rough field guide

Keegan Knittle

University of Helsinki

In this special issue, Marie Johnston (2014) describes the increasing number of tools that behaviour change researchers have at their disposal to specify the contents, proposed mechanisms and modes of delivery of the behaviour change interventions (BCIs) they develop – including the v1 taxonomy of behaviour change techniques (BCTs) (Michie et al., 2013), the CONSORT and SPIRIT statements (Boutron et al., 2008; Chan et al., 2013) and the TIDieR checklist (Hoffman et al., 2014). When used universally, these tools will improve the precision of BCI reporting, and allow for greater replicability of BCIs in research and implementation. Despite this, incomplete reporting of adherence to protocols and the fidelity of BCI delivery still limit the advance of behaviour change science.

Treatment fidelity refers to a number of aspects of *actual* BCI delivery, as opposed to the *ideal* way BCIs are set forth in protocols. This includes factors such as the length of time spent delivering a BCI to each individual, the specific components (BCTs) of a BCI that were *actually* delivered, the order and quality of the delivery of these BCTs, and the way in which the BCTs were received and acted upon by the recipients of the BCI. While the importance of each of these factors has been described previously (Bellg et al., 2004; Moncher & Prinz, 1991; Nelson, Cordray, Hulleman, Darrow, & Sommer, 2012), precious little headway has been made in terms of requiring fidelity reporting in randomized controlled trials (RCTs) of BCIs. This article will discuss some specific examples of why promoting, documenting and reporting fidelity are important, provide an outline of common methods for doing so, and finally, recognizing that fully

detailed reporting of BCI fidelity may not always be possible, provide some key points for how to assess and account for fidelity when resources are limited.

What's all the fuss about?

According to the UK Medical Research Council framework for developing and evaluating complex interventions to improve health (Craig et al., 2008), achieving high fidelity of delivery should be achieved in a pilot phase before carrying out a full-fledged RCT. In real-life however, limited resources mean that a full piloting phase to improve fidelity is not always undertaken, and in the context of RCTs, variations in delivery (i.e. infidelity) can and do occur. In an ideal world, a BCI that contained BCTs A, B & C would be delivered uniformly to all recipients: Techniques A, B & C would be utilised in the same way and delivered in the same order as pre-specified in a protocol. Consider however these cases: Some participants did not receive C because the time for the session had run out; others received A, B & C, but in a different order (e.g. CAB or BCA); and others still received A, B & C, but also techniques D, E & F which were not mentioned in the protocol at all. Each of these scenarios is realistic when delivering a BCI, and such variations in delivery can affect outcomes and treatment effectiveness. When not properly accounted for and reported, as is often the case at present, infidelity effectively removes the 'control' from RCTs of BCIs and limits the advance of behaviour change science.

Apart from the questions of *whether* and *when* a BCT was actually delivered, the question of *how* it was delivered is also significant. Take for example

behavioural goal setting (BCT 1.1 from Michie et al., 2013), which is included in a majority of BCIs. Numerous factors of goal content can influence behavioural performance, including specificity, difficulty level, and ownership (Latham & Locke, 1991; Maes & Karoly, 2005). Although the setting of SMART behavioural goals (Bovend'Eerdt, Botell, & Wade, 2009) is mentioned in many protocols, actual goal content in BCIs is rarely reported, and infidelity in this domain (non-SMART goal setting) may covertly reduce behavioural performance. Variance in information provision (BCTs 4.1, 5.1, 5.3, 5.6, 6.3) might also affect behavioural performance. Consider the differences between clinician 1 who provides information by giving participants a leaflet, clinician 2 who supplements the leaflet with further information given verbally, and clinician 3 who uses the elicit-provide-elicited structure from motivational interviewing – first asking the participant what he or she already knows about the topic and supplementing this (if necessary) with verbal information and finally a leaflet (Rollnick, Miller, & Butler, 2008). Clearly, these differences in how BCTs are delivered have the potential to affect outcomes and intermediate predictors of outcomes, and should in some way be taken into account when reporting the results of an RCT.

Finally, some BCTs require that participants carry out particular actions on their own in order for behaviour change to occur (Hankonen et al., 2014). Self-monitoring of behaviour (BCT 2.3) is one clear example of this. When coupled with other techniques from control theory (Carver & Scheier, 1982), self-monitoring has been linked to greater improvements in physical activity and dietary outcomes than other interventions (Michie et al., 2009). Unfortunately however, self-monitoring is not always completed by the recipients of BCIs. In fact, within weight loss interventions, rates of self-monitoring for diet, exercise and self-weighting are only around 50% (Burke, Wang, & Sevick, 2011). The effectiveness of BCIs which include self-monitoring may therefore suffer, as incomplete or absent self-monitoring would

have knock-on effects on the efficacy of other techniques derived from control theory. Without self-monitoring records to draw from, feedback on behaviour cannot be given, and any behavioural goals that are subsequently set have the potential to be either too difficult or too easy, thus detracting from behavioural performance (Maes & Karoly, 2005). It is therefore not surprising that rates of self-monitoring completion have been shown to significantly predict intervention effectiveness (Burke et al., 2011).

How can fidelity best be promoted and assessed?

Infidelity in intervention delivery, when unaccounted for, has the potential to produce misleading results in RCTs. Researchers must therefore work to promote fidelity (and account for infidelity) at all stages: during BCI development, during piloting and full-scale testing, and during reporting and analyses. This section outlines some of the steps that can be taken at each phase to promote, assess and report fidelity of BCI delivery, many of which have been previously described elsewhere (Bellg et al., 2004; Moncher & Prinz, 1991; Nelson et al., 2012).

Promoting fidelity should begin well before the first participant is recruited. Creating detailed protocols, treatment manuals and sequential intervention materials (e.g. workbooks) provides a blueprint for the intended providers of the BCI. Reviewing these materials within a small group of potential providers can help to refine the materials and improve their clarity and detail. Small group settings also help to identify perceived skill deficits on the part of the providers so that methods to train providers can be optimised. When training providers to deliver a BCI, a building block approach is warranted, with each component BCT discussed individually and in the context of other frequently co-occurring BCTs. Providing training in a group format allows for role plays and rehearsal of key

skills, and provides ample opportunities for peer feedback. Video recording can be used to provide for self-observation and feedback if deemed appropriate. Upon completion of training, ensure that all providers achieve a pre-specified standard of competence by assessing knowledge and/or actual fidelity of delivery in role plays or with mock participants, and develop or identify existing tools to examine this (e.g. quizzes, checklists, self-report questionnaires).

After achieving the pre-specified standard of fidelity in training, a piloting phase allows for observation and assessment of BCI delivery *in vivo*. Where consented to by intervention recipients, record intervention sessions to identify whether the BCI is being delivered as specified in the protocol, and provide feedback to providers on areas which are delivered well and on those that could be improved. Allow providers the opportunity to view or listen to their own recordings in order to analyse their performance, identify barriers to fidelity, and develop coping plans on how to overcome similar barriers in the future. Note down commonly occurring deviations from the protocol and adjust or supplement existing training mechanisms to improve these aspects when training subsequent providers. Conduct exit interviews or administer questionnaires to participants to assess their thoughts about the importance and utility of the various BCTs, as well as ways they might be improved or expanded upon.

Once full-scale testing of the BCI begins, the task of researchers should shift toward monitoring fidelity, so that this can be recorded and reported with the results of the trial, and so that appropriate measures can be undertaken to maintain fidelity of delivery throughout the trial. Ask providers and recipients to complete a checklist after each session to assess whether or not they thought each BCT had been delivered (Presseau et al., 2014). This allows for the examination of differences in perception between providers and recipients, and can act as a reminder for providers about exactly what their tasks in delivering the intervention are. Observe and note the quality of participant-provider interactions (e.g.

provider warmth, directive versus collaborative approach, time spent talking) (Silva, Marques & Teixeira, 2014, this Issue). Use objective measures of fidelity where possible, and just as during the piloting phase, use the results to periodically provide feedback to providers.

Assessing fidelity of BCTs such as self-monitoring which require effort on the part of patients is particularly important during this phase. Ask participants to return completed self-monitoring diaries, make photocopies of these and note down when they are not returned. Monitor how incomplete and absent self-monitoring diaries affect the progress of a session, and whether there are differences between providers in how this is handled. If a BCI is delivered via the internet or on a mobile device, ensure that the website or mobile app has the capability to track the extent to which users engage with intervention components and self-monitoring tools. When a BCI includes goal setting, record the content of goals that participants set, and assess whether characteristics of these goals (e.g. SMARTness) are linked to behavioural outcomes. Use interviews or questionnaires to examine the extent to which participants make use of BCTs outside the formal intervention setting.

Once completed, report the results of the RCT and measures of fidelity as comprehensively as possible. At a minimum, provide a table which identifies the percentages of participants who received each BCT at each time point, including BCTs that were delivered but not included in the protocol (for an example, see Knittle, 2014). Provide data on the extent to which participants engaged with BCTs, such as self-monitoring completion rates, and attempt to link this to outcomes (Hankonen et al., 2014). Provide data on the length of sessions and the quality of participant-provider interactions. When possible, publish data on fidelity and outcomes as supplementary files *on a per-participant basis* (i.e. in a manner you would expect to find in a study using *n-of-1* methodology), so that fine grain detail of the BCI is available for further analysis and inclusion in meta-analyses. With all of

this data collected, it then becomes easy to analyse the extents to which fidelity of BCT delivery, participant engagement with BCTs, intervention duration and order of BCT delivery contribute to the efficacy of the BCI as a whole.

Gee, that seems like a lot...

Indeed, fully accounting for fidelity in BCIs is a big job, and requires additional resources beyond those needed to simply deliver an intervention. Researchers should therefore account for this when budgeting for grants and planning to develop or test BCIs. While the extension of the CONSORT statement for non-pharmacological treatments includes reporting the 'details of how adherence of care providers with the protocol was assessed or enhanced' (Point 4C; Boutron et al., 2008), it does not provide any further specifics about the required content of these reports. In a perfect world, all research teams would undertake all of the aforementioned activities (and more) to promote, assess and report on fidelity, but this is not always possible. Luckily, hope remains for those with limited resources and who have not budgeted for this in advance. The end of this article provides a list of key points that can be used as a guide for tackling fidelity if you're in a pinch or don't have the resources to assess fidelity for all participants.

An alternative view of the importance of fidelity

While fidelity of BCI delivery is clearly important and can affect outcomes, infidelity almost invariably occurs, and RCTs of BCIs therefore provide very little in the way of actual control. Does this mean that behaviour change science is at an impasse until BCIs can ensure 100% fidelity? No. On the contrary, when properly recorded, this individual variation in delivery (e.g. duration, *actual* BCT delivery, and order

and quality of BCT delivery) provides the opportunity for natural experiments within the context of each RCT. Which components of a BCI actually drive its effectiveness? Is there a critical mass of BCTs which needs to be delivered to ensure behaviour change? Which characteristics of participant-provider interactions make the most difference? While it would be impossible to answer all of these questions within one individual RCT, a decade worth of well-reported 'natural experiments' in BCIs, reported in a comprehensive way, would empower subsequent meta-analyses to properly investigate these fine inner-workings. An accumulation of open-access data with a high level of detail on fidelity and outcomes at the *per-participant* (n-of-1) level is therefore paramount to advancing behaviour change science to the next level.

Key Points for promoting and assessing fidelity (on a budget)

- Provide a checklist of BCTs for providers to use during sessions.
- Assess delivery of BCTs via a questionnaire to patients and/or providers after the session.
- Assess a subset of intervention sessions from each provider (as opposed to all participants).
- Focus on the fidelity of BCTs hypothesized to have the greatest effects on outcomes (e.g. self-monitoring, goal setting, action planning, problem solving).
- Use questionnaires to assess participants' use and enactment of BCTs outside of the intervention sessions.
- Provide detailed fidelity and outcome data at the per-participant level.

References

Bellg, A. J., Borrelli, B., Resnick, B., Hecht, J., Minicucci, D. S., Ory, M., ... & Czajkowski, S.

- (2004). Enhancing treatment fidelity in health behavior change studies: best practices and recommendations from the NIH Behavior Change Consortium. *Health Psychology, 23*(5), 443. doi:10.1037/0278-6133.23.5.443
- Boutron, I., Moher, D., Altman, D. G., Schulz, K. F., & Ravaud, P. (2008). Extending the CONSORT statement to randomized trials of nonpharmacologic treatment: explanation and elaboration. *Annals of Internal Medicine, 148*(4), 295-309. doi:10.7326/0003-4819-148-4-200802190-00008
- Bovend'Eerdt, T. J., Botell, R. E., & Wade, D. T. (2009). Writing SMART rehabilitation goals and achieving goal attainment scaling: a practical guide. *Clinical Rehabilitation, 23*(4), 352-361. doi:10.1177/0269215508101741
- Burke, L. E., Wang, J., & Sevick, M. A. (2011). Self-monitoring in weight loss: a systematic review of the literature. *Journal of the American Dietetic Association, 111*(1), 92-102. doi:10.1016/j.jada.2010.10.008
- Carver, C. S., & Scheier, M. F. (1982). Control theory: a useful conceptual framework for personality-social, clinical and health psychology. *Psychological Bulletin, 92*(1), 111-135. doi:10.1037/0033-2909.92.1.111
- Chan, A. W., Tetzlaff, J. M., Altman, D. G., Laupacis, A., Gøtzsche, P. C., Krleža-Jeric, K., ... & Moher, D. (2013). SPIRIT 2013 statement: defining standard protocol items for clinical trials. *Annals of Internal Medicine, 158*(3), 200-207. doi:10.7326/0003-4819-158-3-201302050-00583
- Craig, P., Dieppe, P., Macintyre, S., Michie, S., Nazareth, I., & Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal, 337*. doi: 10.1136/bmj.a1655
- Hankonen, N., Sutton, S., Prevost, A. T., Simmons, R. K., Griffin, S. J., Kinmonth, A. L., & Hardeman, W. (2014). Which behavior change techniques are associated with changes in physical activity, diet and body mass index in people with recently diagnosed diabetes? *Annals of Behavioral Medicine, 1-11*. doi:10.1007/s12160-014-9624-9
- Hoffmann, T. C., Glasziou, P. P., Boutron, I., Milne, R., Perera, R., Moher, D., ... & Michie, S. (2014). Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ, 348*. doi: 10.1136/bmj.g1687
- Johnston, M. (2014). Improving the reporting of behaviour change interventions. *The European Health Psychologist, 16*(5), 181-189.
- Knittle, K. (2014). We cannot keep firing blanks—yet another appeal for improved RCT reporting: commentary on Peters, de Bruin and Crutzen. *Health Psychology Review*. doi:10.1080/17437199.2014.900721
- Latham, G. P., & Locke, E. A. (1991). Self-regulation through goal-setting behavior. *Organizational Behavior and Human Decision Processes, 50*(2), 212-247. doi:10.1016/0749-5978(91)90021-K
- Maes, S., & Karoly, P. (2005). Self-regulation assessment and intervention in physical health and illness: a review. *Applied Psychology, 54*(2), 267-299. doi:10.1111/j.1464-0597.2005.00210.x
- Michie, S., Richardson, M., Johnston, M., Abraham, C., Francis, J., Hardeman, W., ... & Wood, C. E. (2013). The behavior change technique taxonomy (v1) of 93 hierarchically clustered techniques: building an international consensus for the reporting of behavior change interventions. *Annals of Behavioral Medicine, 46*(1), 81-95. doi:10.1007/s12160-013-9486-6
- Moncher, F. J., & Prinz, R. J. (1991). Treatment fidelity in outcome studies. *Clinical Psychology Review, 11*(3), 247-266. doi:10.1016/0272-7358(91)90103-2
- Nelson, M. C., Cordray, D. S., Hulleman, C. S., Darrow, C. L., & Sommer, E. C. (2012). A procedure for assessing intervention fidelity in experiments testing educational and behavioral interventions. *The Journal of Behavioral Health Services & Research, 39*(4), 374-396. doi: 10.1007/s11414-012-9295-x
- Presseau, J., Hawthorne, G., Sniehotta, F. F., Steen, N., Francis, J. J., Johnston, M., ... & Eccles, M. P.

- (2014). Improving diabetes care through examining, advising, and prescribing (IDEA): protocol for a theory-based cluster randomised controlled trial of a multiple behaviour change intervention aimed at primary healthcare professionals. *Implementation Science*, *9*(1), 61. doi:10.1186/1748-5908-9-61
- Rollnick, S., Miller, W. R., & Butler, C. (2008). *Motivational interviewing in health care: helping patients change behavior*. New York: Guilford Press.
- Silva, M. N., Marques, M. M., Teixeira, P. J. (2014). Testing theory in practice: the example of self-determination theory-based interventions. *The European Health Psychologist*, *16*(5), 171-180.



Keegan Knittle
University of Helsinki, Finland
keegan.knittle@helsinki.fi