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Issues arising in the evaluation of digital behaviour change interventions

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It may not be immediately obvious why digital behaviour change interventions (BCIs) should not be evaluated in exactly the same way as any other behaviour change interventions. The aim of this paper is therefore to consider the parallels and differences between BCIs delivered in person and BCIs delivered by means of the internet (and other digital media), and the implications these differences have for the evaluation of digital BCIs. Five aspects of BCIs and their evaluation will be considered: the aims, and therefore intended outcomes, of the BCIs; the mode and process of delivery; the method of recruitment and characteristics; resulting sample methods of assessment; and approaches to analysis of intervention effects.

Aims and intended outcomes

It can be assumed that since the aim of any BCI must be to change behaviour, digital BCIs, like other BCIs, should evaluate change in behaviour itself (Glasgow, 2007). There is now consensus (Michie, Rothman, & Sheeran, 2007; Yardley & Moss-Morris, 2007) that evaluation of BCIs should also include assessment of the effects of the intervention on the antecedents of behaviour that are likely to have mediated intervention effects, such as changes in If long-term behaviour attitudes or self-efficacy. change is intended, it is also desirable to evaluate maintenance as well as initiation of the target behaviour (Glasgow, Klesges, Dzewaltowski, Bull, & Estabrooks, 2004), although long-term follow-up by internet can pose particular problems (see below).

These outcome measures are common to all BCIs. However, from the outset, the internet has been valued for its potential to empower lay users. This ethos is reflected in Eysenbach's manifesto (2001) setting out the '10 Es' as defining characteristics that e-Health programmes should aspire to: efficiency; enhancing quality; evidence-based empowerment; encouragement; education; enablement; extending access; ethics and equity. Not all of these aims would be typical of traditional health-care BCIs, which are often less userled and more focused specifically on either health or behavioural outcomes.

A systematic review of 37 digital health-related BCIs (Griffiths, Lindenmeyer, Powell, Lowe, & Thorogood, 2006) confirmed that the rationale for

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digital BCIs frequently did include aims of this kind, such as providing more timely and convenient access for users, reaching isolated or stigmatised groups, and reducing provider costs. However, the authors of the review note that few digital BCIs actually evaluate the extent to which these wider aims are achieved. If the intended outcomes of digital BCIs include these broader objectives then it is clearly important that they should be included in the assessment of outcomes.

Process of delivery

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There is consensus that the first step in the development of all BCIs should be to ensure - and report - that the intervention incorporates behaviour change techniques which theory and previous research indicate should be relevant to behaviour change (Craig et al., 2008; National Institute of Health and Clinical Excellence (NICE), 2007). Consequently, in common with other BCIs, evaluation of digital BCIs should include some description and assessment of the theoretical and empirical basis for intervention components. There is some evidence that this important step may currently be omitted from the development of many digital BCIs (Evers, Cummins, Prochaska, & Prochaska, 2005).

In face-to-face BCIs, an equally important aspect of the process of delivering an intervention is the extent to which the intervention is effectively implemented as intended. This may include ensuring intervention have that those delivering the appropriate qualifications and credentials, have >



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the skills necessary (e.g. therapeutic and communication skills) and closely follow instructions for intervention delivery (Davidson et al., 2003; Glasgow et al., 2004). In digital BCIs, the issue of effective intervention implementation is equally important, and an advantage is that the entire content and format of the intervention is explicit and standardised. However, the factors affecting the effectiveness of delivery are rather different. For example, to replace the authority and trust inspired by delivery of an intervention by health professionals in a clinic setting, a health intervention website may need to present the credentials of the authors and sources, or seek endorsement from a trusted independent body such as the Health on the Net Foundation. Instead of good interpersonal communication skills to deliver an intervention effectively, a digital BCI needs to be accessible to all (including those with disabilities and lower health and computer literacy levels) and be clear and easy to navigate, drawing on human factors principles to optimise usability (Lin, Choong, & Salvendy, 1997). The intervention must anticipate the needs of a variety of users, containing all the required elements to persuade and support users, including when necessary links with peers or professionals, and choice of alternative options or additional information.

A further consideration when evaluating how an intervention is implemented in practice is the extent to which users understand and adhere to the intervention, which may be affected by their abilities and motivations, and whether they attend to and follow the advice given. Digital BCIs offer opportunities for examining adherence in great detail, as it is possible to objective record not only how often a website is visited (the most widely used measure of adherence), but also what features of the website were used, what data was entered, which pathways were followed, and how long was spent on each section. Analysis of this information can provide useful insights into what elements of a digital BCI are most effective in changing behaviour, and whether it is preferable to constrain users to view essential pages or to allow them to choose from a rich set of resources (Severson, Gordon, Danaher, & Akers, 2008).

Sample characteristics and assessment methods

The gold standard for evaluating BCIs delivered in person is to recruit a random sample of the target population, and use objective independent measurement of the outcome of the intervention in almost all participants. In digital BCIs it is seldom possible to achieve this. Unless an existing sampling frame has been used (such as workplace employees), participants are typically self-selected volunteers who happen to have come across the website on the internet or through advertising. Participants may be very widely dispersed geographically - often from around the world - making follow-up using objective measurement rather than self-report impossible. There is the potential for identity fraud, and for users to register more than once in the hope of being randomised to their preferred intervention arm, and it may be very difficult to detect this if different computers are used (Bowen, Daniel, Williams, & Baird, 2008). Moreover, dropout before follow-up is usually high despite the best efforts of researchers, typically exceeding the 10-20% which face-to-face interventions can realistically aim for (Vandelanotte, Spathonis, Eakin & Owen, 2007).

While remote, automated assessment has potential disadvantages with regard to objective measurement, identity fraud and dropout rates, it does also have some potential advantages. In-person assessment carries the risk of unintentional researcher influence on responses, with the consequence that often part or all of the follow-up is administered remotely, by postal questionnaire. Internet follow-up avoids the problem of researcher influences on responses, and rates of missing data are typically much lower than with postal administration of questionnaires, since the programme can require users to complete questions they have omitted. However, it is therefore important to be aware that the way people respond to a questionnaire over the internet can differ systematically from their response to the same questionnaire administered in a different setting (Vallejo, Jordán, Díaz, Comeche, & Ortega, 2007) and caution must be taken if response patterns are compared. For example, people responding remotely may be less anxious, or more willing to admit socially undesirable behaviours such as nonadherence or risky behaviour.

Approaches to analysis

The differences between digital BCIs and BCIs person delivered described above in have implications for how analysis of outcomes can and should be approached. Currently, meta-analyses of internet-delivered interventions tend to show significant effects but large heterogeneity. This may partly reflect our current ignorance regarding what are the most important variables to use for tailoring or the most effective formats and media for communication - and of course these are likely to differ for different behaviours and populations. Traditional randomised controlled trials must undoubtedly play a part in contributing to our understanding of what works, for whom.

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However, there are often considerable obstacles (described above) to carrying out traditional gold standard RCTs, whereas digital BCIs offer new and exciting opportunities for different approaches to analysing intervention effects.

The best digital interventions offer users some choices, and 'tailor' the information and advice provided to the beliefs, preferences or circumstances of the individual (Kreuter, Farrell, Olevitch, & Brennan, 2000). Many researchers have suggested that therefore evaluation of interventions must take into consideration the fact that users will have experienced rather different interventions, depending on the responses they gave and the choices they made. One way to examine the effects of subcomponents of the intervention is to use a fractional factorial experimental design (Collins, Murphy, & Strecher, 2007). Another is to use an observational design to identify how usage of particular intervention components may influence outcome. Large samples are ideally required for analysis of mediators and moderators of outcome - and automated interventions delivered by internet to a potentially huge population provide an opportunity to collect the sample sizes required. Recently developed software (www.lifeguideonline.org) can support this process of digital intervention evaluation. The software allows researchers to easily create and test different versions internet-delivered interventions, of provides opportunities for creating large pooled datasets from interventions using the same or similar components, and permits detailed analysis of the usage of each part of the intervention by every individual.

Conclusions

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Digital BCIs share many features with BCIs delivered in person, but it is important to recognise that they also raise new considerations for evaluation. They may have different aims, and the mode of delivery necessitates developing expertise in new ways of communicating. They can be difficult to evaluate using traditional RCT designs, but they offer new opportunities for examining more precisely the effects of intervention components, at the level of the individual or using large samples.

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