AGING AND MENTAL HEALTH

EDITORIAL

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Raising the standard of applied dementia care research: addressing the implementation error

Introduction

Current methodology has made popular the pragmatic randomized trial (Foster & Little, 2012) and has led to an acknowledged growth of high-quality research in the'new generation' of psychosocial interventions in dementia care (Orrell, 2012). However, many trials of psychosocial interventions in dementia lack impact. It is not clear whether this reflects a genuine ineffectiveness, since the methodology used in dementia care research is at resent weak in addressing the important distinction between genuine ineffectiveness and an implementation error. Therefore, potentially effective dementia care interventions that may have a positive impact on patient experience can fail to show effectiveness, thereby reducing treatment options and wasting research money.

Methodological discussions about the success and failure of interventions in dementia care within the European INTERDEM group of multi-professional researchers on psychosocial dementia care (www.interdem.org/) led to acritical analysis of the suitability of the current methodology. This has often relied on the Medical Research Council's (MRC) Framework for complex interventions and its iterations (Campbell et al., 2000; Craig et al., 2008; Craig & Petticrew, 2013). Foster and Little (2012) pinpoint an important obstacle to improving clinical practice as the legacy of 'simple' drug therapy evaluations which are engrained in the design and conduct of the pragmatic trial, a view that can also be extended more generally to the interpretation and conduct of the MRC framework for complex interventions and its methodologies. The advantage of pragmatic trials is their proximity to daily practice in routine health care settings. This has particular implications for the design and conduct of psychosocial intervention research in dementia, where the important distinction between poor attention to implementation and genuine ineffectiveness is often overlooked.

Furthermore, better attention to the implications of this proximity in the design and conduct of psychosocial intervention research trials may reduce the need for a separate large-scale implementation study phase in the way that this is currently conceived within the MRC approach to complex interventions (Craig et al., 2008; Craig & Petticrew, 2013).

This is an urgent issue for psychosocial intervention research in dementia care as today 35.6 million people and families worldwide live with dementia (Prince et al., 2013), whilst major pharmaceutical advances in prevention and cure remain elusive (Miller, 2012). The predicted future growth of dementia cases over the next decade will undoubtedly raise the already high costs of care, estimated at US$ 604 billion in 2010 (Wimo et al., 2013), in an illness that is most feared people over the age of 55 years (Le Couteur, Doust, Creasey, & Brayne, 2013), since it can undermine core human capacities resulting in decline in quality of life (Selkoe, 2012). Although cure for dementia is not available for dementia patients, we are not empty handed. Psychosocial intervention research has emerged as today's forerunner, given its aim to improve daily practice among professionals who provide support to people and families living with dementia. Psychosocial interventions in dementia involve interactions between people to improve psychological and social functioning (Moniz-Cook, Vernooij-Dassen, Woods, & Orrell, 2011; Rabins et al., 2007), such as cognitive stimulation therapy (Woods, Aguirre, Spector, & Orrell, 2012), occupational therapy (Graff et al., 2006) and

support programmes for family carers (Vernooij-Dassen, Draskovic, McCleery, & Downs, 2011).

This paper outlines the rationale for a paradigm shift in the design and methodology for evaluation of complex interventions in applied dementia care research. We use psychosocial intervention research as an exemplar of how researchers and their funders may achieve better value for money.

Success and failure of psychosocial interventions

Psychosocial interventions are most effective when tailored to the individual needs of the person and family (Olazaran et al., 2010). Positive effects are demonstrated on patient cognition (effect size 0.59, n ¼ 67), patient behaviour (effect size 0.60, n ¼ 62) (Olazaran et al., 2010) and family carer mood (effect size _0.66, n ¼ 294) (Vernooij-Dassen, Draskovic, et al., 2011). Moreover, they reduce costs by delaying institutionalization (effect size OR 0.59, 95% BI 0.43–0.81) (Spijker et al., 2008). However, many studies fail to report positive outcomes (Olazaran et al., 2010). For example, recent pragmatic trials of support programmes (Kurz et al., 2012; Low et al., 2013; Van de Ven et al., 2013; Waldorff et al., 2012), telecare (Bardsley, Steventon, & Doll, 2013), training interventions (Beer et al., 2011; Spijker et al., 2011) and system enhancements or novel methods of delivering services (Goldberg et al., 2013; Meeuwsen et al., 2012; Nourhashemi et al., 2010; Van Houdt & De Lepeleire, 2010) all report no positive effects compared with the control 'usual care' condition. One study nonetheless demonstrated improvements in the patient experience and family carer satisfaction (Goldberg et al., 2013) whilst others point to problems with delivery of the intervention by practitioners such as poor adherence and variation in practice (Low et al., 2013; Spijker et al., 2013; Wenborn et al., 2013). Thus, failure to report positive outcomes may reflect genuine ineffectiveness where the intervention has failed to address basic human values such as dignity and autonomy (Vernooij-Dassen, Leatherman, & Rikkert, 2011) or may be a consequence of practical difficulties in conducting applied research in routine care settings (Iliffe et al., 2008). This latter phenomenon is known as an implementation error which refers to low treatment fidelity, meaning that the application of the intervention differs considerably from the original plan (Hulscher, Laurant, & Grol, 2005).

The weakness in current methodologies for evaluation can be observed where an implementation error is overlooked during pragmatic trials of effectiveness. A particular aspect that is often ignored is the importance of the practitioners who deliver interventions. The world of health care professionals, with their multiple and competing demands within routine care settings, has obvious impacts on treatment fidelity and the assumption that interventions are always carried out to plan is at best, naive. To establish how research can do more for today's dementia patients and families, better knowledge is required about treatment fidelity including the interactions of practitioners with people with dementia and families and the way they deliver the intervention.

Treatment fidelity

Randomized and cluster randomized control trial (RCT or cRCT) designs have improved the standards and quality of psychosocial intervention research. They focus on minimizing the risk of type I (rejection of a null hypothesis that is in fact correct) and type II (acceptance of a null hypothesis that is in reality false) errors, but rarely on problems of fidelity to the intervention protocol. Reporting of fidelity has been weak (Turner, Shamseer, Altman, Schulz, & Moher, 2012) and where this has been reported, treatment fidelity varies from 18% to 100% (Perry et al., 2011). This introduces the risk of an implementation error. Implementation science places an implementation error as equivalent to type I and II errors, naming this 'the type III error' (Hulscher et al., 2005). Implementation errors threaten internal validity and undermine the credibility of an otherwise successful intervention, thus rendering

effect analyses and positive outcomes meaningless (Moniz-Cook et al., 2008), with associated wasted effort and resources (Glasgow, Klesges, Dzewaltowski, Estabrooks, & Vogt, 2006).

Explaining variation in fidelity goes some way towards minimizing type III errors. Variation may relate to the level of control over the intervention. Zwarenstein and colleagues (Zwarenstein et al., 2008) outline two types of trials where the control of setting and treatment fidelity is crucial: explanatory (high control) and pragmatic (low control) trials. Explanatory trials demonstrate efficacy or potential (in) effectiveness of an intervention in an 'ideal setting with a closely monitored intervention, whilst pragmatic trials inform us about the effectiveness, in the context of daily practice. An example of high control over delivery of the intervention is seen in a recent study of a successful family care support programme where practitioners were recruited to deliver the intervention, with no other apparent competing demands. The authors outline a procedure for regular clinical supervision of practitioners with systematic ongoing attention to poor fidelity (Livingston et al., 2013).

Conducting psychosocial intervention research in dementia care requires improved clarity of methods that properly address levels of control over the intervention when delivered by the growing range of practitioners including health and social care professionals. For example, the landmark review of non-pharmacological therapy in dementia demonstrates that effective studies were highly controlled and used a limited number of welltrained practitioners (interventionists) combined with monitoring or team-based social control (Olazaran et al., 2010).. Moreover, explanatory trials carried out by a limited number of interventionists with strict application of the intervention protocol demonstrate strong positive effects, whilst pragmatic trials of a similar intervention delivered by numerous interventionists with poor treatment fidelity fail to demonstrate equivalent outcomes (Graff et al., 2006; Voigt-Radloff et al., 2011).

Why is treatment fidelity low? Studies of barriers to treatment fidelity within RCTs provide some clues. These highlight the importance of accounting for the context of daily practice including: patient characteristics (Voigt-Radloff et al., 2011); time constraints, motivation and opportunity for shared decision making by professionals (Spijker et al., 2013); the social setting (Spijker et al., 2013); the economic and organizational context; and use of implementation strategies (Leontjevas et al., 2013; Spijker et al., 2013; Voigt-Radloff et al., 2011). A striking finding is that barriers noted in pragmatic trials are similar to those found in implementation studies (Grol, Wensing, Eccles, & Davis, 2013).

There is a growing interest in the contribution of implementation science to applied research in health care, although at present this appears to be limited to outlining the range of strategies that are available to the researcher (Peters, Adam, Alonge, Agyepong, & Tran, 2013). We suggest that psychosocial intervention research can benefit from knowledge derived from implementation studies. Topics in implementation science can be emphasized early in the MRC framework, by an improved association between the developmental and feasibility testing phase, where the latter could include aspects of: treatment fidelity; practitioner behaviour; and potential contextual factors that may help or hamper delivery of the intervention. Single-case studies at the developmental phase are a good example of where the researcher can test the success and failure of an intervention (Moniz-Cook, Woods, & Richards, 2001). However, this would be of little practical use if the feasibility and pilot studies do not then include methods to address identified contextual factors in order to overcome the obstacles and reinforce facilitators in the delivery of the intervention. Only then can the evaluation phase be embarked upon.

In order to avoid the type III implementation error in the evaluation phase, we propose a paradigm shift in the design of studies at the evaluation and implementation phases of

complex interventions. This can be achieved at the evaluation phase by studies that first test the efficacy of an intervention and then its effectiveness (see Table 1).

Table 1. a refined methodology for complex psychosocial intervention research trials.

MRC 2013	Refined methodology
Developmental • Identifying the evidence base • Identifying or developing theory • Modelling process and outcomes	Developmental • No change
Feasibility and piloting • Testing procedures • Estimating recruitment and retention • Determining sample size	Feasibility and piloting • Analyse practical issues such as practitioner behaviour and contextual factors noted in modelling process and outcomes that may help or hamper delivery of the intervention • Testing procedures • Estimating recruitment and retention • Determining sample size
Evaluation Assessing effectiveness Understanding change process Assessing of cost effectiveness	Evaluation Assessing efficacy – explanatory trial • 'Ideal setting(s)' – motivated practitioners, patients and services • Anticipated barriers and facilitators prior to intervention by stakeholders (service managers, professionals and patients) • Testing of strategies to stimulate the use of the intervention • Highly controlled by monitoring use of intervention • Evaluation of barriers and facilitators perceived by – dissemination implicit in the procedure • Controlled or randomized controlled trial (RCT) Evaluation of effectiveness – pragmatic trial • Analysis of stakeholders – dissemination implicit • Identification of anticipated barriers and facilitators • Contextualizing intervention to stakeholders • Use of strategies to overcome barriers • Training of practitioners • RCT or cluster RCT • Surveillance, monitoring, follow-up if possible Understanding change process • 'Ideal setting(s)' – motivated practitioners, patients and services Assessing of cost effectiveness
Implementation • Dissemination • Surveillance and monitoring • Long-term follow-up	Implementation • Implementation methodology already included in pragmatic trial • Dissemination of intervention and strategies to stimulate widespread use of the intervention according to its protocol • Surveillance, monitoring and audit included in dissemination
Developmental • Identifying the evidence base • Identifying the developing theory • Modelling process and outcomes	Developmental • Use theory to understand findings for stakeholders or services settings where the intervention was weak (eg use drop out data, patient views, poor outcomes etc.) • Development of new innovation considering previous barriers • Modelling process and outcomes.

Where next?

In contrast to the MRC framework we suggest that researchers should precede a pragmatic trial with a well designed explanatory trial in which the mechanisms for practitioner behaviour are highly controlled and studied. This has the advantage of minimizing type III errors by introducing implementation methodology at the preliminary trial phase (Table 1). Here,

implementation methodology can guide careful study of the process of delivery of an intervention including: the 'ideal' setting where motivated target stakeholders (such as practitioners, patients, families and service providers) have been selected; study of anticipated barriers and facilitators outlined by participating stakeholders prior to the intervention; and testing of strategies to facilitate intervention uptake (such as leadership, supervision and stakeholder engagement). Strategies such as preparatory practice activity to train interventionists in delivery of the intervention can also be tested (Borrelli, 2011) to determine what level of monitoring will be needed to enhance fidelity and changes in practitioner practice in the final large-scale trial, which ideally should be widespread and consider cluster designs. The recent notion of an effectiveness-implementation hybrid design (Curran, Bauer, Mittman, Pyne, & Stetler, 2012) also emphasizes the importance of including implementation strategies within a final large-scale 'pragmatic' trial, but this type of design continues to overlook the need for systematic study of the practical barriers experienced by stakeholders in their own varied settings and contexts. These need to be properly understood in detail before strategies to overcome these can be identified. We suggest that stakeholder views and behaviour are important and should be studied first during the explanatory trial, prior and after the intervention. Guidance on how to assess clinical governance and intervention fidelity to enable researchers to improve rigour (Charlesworth, Burnell, Hoe, Orrell, & Russell, 2013) can also be used at this stage. Moreover, the researcher also has the opportunity for more detailed study of patient adherence and drop out which may allow for better targeting of individualized interventions through examination of socio-cultural factors, co-morbid health conditions, timing (i.e. when in the patient journey the intervention was offered), suitability of the intervention to particular patients and families as well as contextual factors such as what other support might be available in 'usual care' settings. A controlled – or a randomized controlled trial where randomization is at patient but not practitioner level, if this can realistically be powered within a relatively small study – can be conducted. The key would be to use a highly motivated 'ideal' group of practitioners and supportive management in the experimental group and a 'normal' or 'usual' control group to test the impact (efficacy) of the intervention.

When the impact is positive, researchers can then proceed to the next stage of evaluation within an adapted pragmatic randomized (or ideally a cluster randomized) controlled trial. This final trial of effectiveness will use implementation research strategies such as starting with an analysis of the setting and the stakeholders, identification of anticipated barriers and facilitators; adaptations to barriers discovered in the explanatory trial and to the anticipated barriers and also methods to strengthen facilitators. These adaptations should be used in the training of the practitioners. Implementation methodology may now be used a priori to minimize type III errors and also during the trial as a means of monitoring delivery. In this way the design of a pragmatic trial may be dynamically harnessed in the real world of service provision. Thus, the pragmatic trial will measure the effect of intervention contextualized to practitioner and patient circumstances whilst the accompanying process analysis will carefully describe application of the intervention and the extent to which its perceived barriers have been overcome and its facilitators strengthened. Within our refined paradigm not only does dissemination become an iterative process that implicitly involved stakeholders throughout but the second evaluation study which tests effectiveness can incorporate methods for surveillance, monitoring, and longer term follow-up, which may in turn contribute to future development of related dementia care innovation.

By reducing a layer of enquiry surrounding implementation within the MRC complex intervention framework (Craig et al., 2008), the aspiration for research findings to do more for patients is facilitated. This paradigm shift is, we suggest, an important avenue for efficiency savings in applied dementia care research programmes such as those funded by the National Institute of Health Research and the Economic and Social Research Council in the UK or the recent European Joint Programme for Neurodegenerative Disease Research http://www.neurodegeneration research.eu/).

Conclusion

People with dementia and families today deserve high quality interventions to live well with dementia, backed up by wise investment in dementia care research (Selkoe, 2012). Given current constraints on budgets and the growing number of people who can benefit from psychosocial interventions, practitioners and service organizations deserve timely attention to their barriers and facilitators in application of a new intervention. Ignoring the role of practitioners who deliver the intervention in their particular contexts will, we suggest, continue to overlook the type III error and thus hamper treatment options for people and their families. We therefore propose a paradigm shift in methodology for psychosocial research where implementation errors are acknowledged and addressed particularly during the evaluation phase. This departs from the MRC framework, starting with slightly better integration of the developmental (i.e. the modelling of process and outcomes) and feasibility phases to include contextual factors and practitioner behaviour in the latter. However we propose significant changes at the MRC evaluation phase. Given our objective to differentiate between genuine effectiveness and implementation error, we outline how this may be achieved with a design that first tests efficacy under highly controlled conditions whilst eliciting and studying the variety of practitioner and patient contexts and then, after adjusting the intervention to the variety of real life contexts, tests effectiveness of this in daily practice. Our paradigm shift future offers opportunities, depending on the findings from the 'effectiveness' study, to render the implementation phase, as it is currently conceived (Craig & Petticrew, 2013) redundant, through identifying and application of theory to the findings and modelling new innovation. This may accelerate the scope for improved delivery of a psychosocial intervention into routine practice.

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