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Comprehensive evaluation of interventions: eight vital parameters

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Abstract

Background It is critically important to determine the effectiveness of an intervention before it can be translated into clinical practice. However, the future implementation and sustainability of the intervention may be diminished if other intervention parameters are not assessed. This requires obtaining feedback from intervention recipients so interventions will be perceived as appealing, relevant, meaningful and beneficial to them; otherwise recipients may be unlikely to perform them over time, resulting in unsuccessful health outcomes.

Aim To propose the addition of two intervention parameters to the existing six-parameter model and provide examples from recent research of how each parameter can be tested.

Discussion Definitions of the eight parameters are provided and methods for analysing each of them explained. While some studies show necessity, fidelity and cost have unique distinguishing characteristics, other studies indicate feasibility, acceptability and safety have common features, and efficacy and effectiveness are closely associated.

Conclusion Researchers frequently examine one or two parameters, but few simultaneously apply the six-parameter model. This model is also missing two vital parameters – efficacy and cost.

Implications for practice Comprehensive and systematic evaluation of all eight intervention parameters is recommended before researchers begin randomised controlled trials and translate them into practice.

Introduction

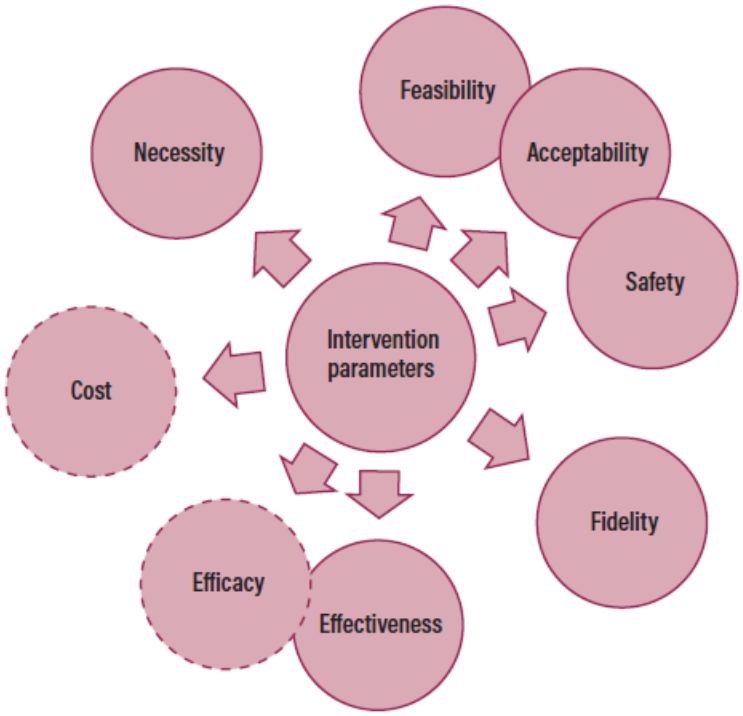
Designing and testing interventions is a large part of nursing research. Development and implementation of evidence-based interventions are important in providing high-quality healthcare to ensure optimal outcomes (Stevens 2013). To this end, nurse researchers commonly create and analyse interventions in clinical environments through a programme of research.

Developing or adapting interventions typically involves an initial step during which certain parameters are examined (Gignac 2007). This examination may reveal a need to modify the intervention before larger randomised controlled trials are conducted and the intervention is translated into practice (Zauszniewski 2012). However, many researchers do not systematically and comprehensively examine more than one or two parameters simultaneously (Gignac 2007, Zauszniewski 2012).

Zauszniewski (2012) proposed a model of six intervention parameters and recommended their systematic, simultaneous investigation before conducting larger clinical trials. The six parameters were: necessity, acceptability, feasibility, fidelity, safety and effectiveness (Zauszniewski 2012). However, we propose two additional parameters for inclusion in that model: rising healthcare costs point to a need to consider the cost of interventions and efficacy, which indicates how an intervention works under ideal conditions (Singal et al 2014), was overlooked in the previous model.

Figure 1 shows the eight-parameter model. The original six parameters are indicated by circles outlined with solid lines, while the two new parameters are indicated by circles outlined by dotted lines. The literature suggests there is potential overlap between feasibility and acceptability, as well as commonalities between efficacy and effectiveness, so Figure 1 depicts these instances with overlapping circles.

Figure 1. Eight intervention parameters



We recommend researchers simultaneously examine all eight intervention parameters as they develop or adapt interventions. However, few published studies have simultaneously examined the six original parameters (Bekhet et al 2012, Musil et al 2015, Pinto et al 2016, Zauszniewski et al 2017) and none have recommended or examined all eight simultaneously. This paper provides definitions of the eight intervention parameters and provides examples of studies describing how individual parameters were evaluated.

Key points

- Before translation into practice, nursing interventions should be thoroughly examined for their necessity, acceptability, feasibility, safety, fidelity, efficacy, effectiveness and cost-effectiveness
- Clinical nurses who are interested in developing practice-based interventions might consider eight intervention parameters to guide their design and implementation of interventions

Necessity

Before developing an intervention, the extent to which it is needed should be considered. This can be done from the perspectives of medical professionals, observers, family members and patients who will receive the intervention (Zauszniewski 2012). For example, medical professionals may use diagnostic procedures and expert knowledge, while family members may rely on their observations and instincts (Krishnan et al 2017). However, only potential recipients can share their views about whether they believe they need a particular intervention. This is critically important because if they do not believe they need a particular intervention, they are unlikely to perform it over time.

Studies show a discrepancy between what healthcare providers prescribe as a necessary intervention and what recipients believe is necessary. For example, when a patient has a medical condition that

warrants pharmacological intervention, but does not believe the medication is needed, non-compliance is likely to occur (Aikens et al 2008); prospective recipients' perceptions of their needs may similarly affect psychosocial interventions (Winzer et al 2009).

Different methods have been described in recent research. To determine patients' need for a spiritual or religious intervention to improve their spiritual well-being, Elham et al (2015) used open-ended questions to assess their life events, perceptions and concerns related to their medical conditions, as well as their spiritual or religious beliefs and practices.

In comparison, Mosleh et al (2017) examined scores on a quantitative learning needs scale that captured physical activity, medications, wound care, diet, complications and risk assessment to determine cardiac patients' potential level of need for future interventions (Mosleh et al 2017).

Acceptability

The acceptability of an intervention is the extent to which people perceive that what they are being asked to do is reasonable or appropriate (Zauszniewski 2012). It reflects the degree to which recipients believe the intervention is preferable to other alternatives (Soucy and Hadjistavropoulos 2017).

Some researchers – for example, Lopez-Gomez et al (2017) – have conceptualised acceptability in terms of sustainability and recipients' satisfaction. It has also been evaluated by qualitative or quantitative ratings obtained from questionnaires, journals and audio recordings (Zauszniewski et al 2013, 2016). Jelinek et al (2017) used a questionnaire to rate the level of enjoyment, relevance, novelty, application to everyday life, usefulness, helpfulness and uniqueness of a meta-cognitive training intervention for outpatients with a depressive disorder. It also used two open-ended questions asking patients to describe what they liked and disliked about the intervention.

However, determining acceptability may also focus on how the intervention is delivered. For example, Soucy and Hadjistavropoulos (2017) evaluated the acceptability of internet-based cognitive behavioural therapy (CBT) compared with traditional CBT and medication by asking primary care patients with health-related anxiety to view vignettes describing each intervention and to rank them according to their personal preferences.

Finally, some researchers have assessed acceptability – as well as feasibility – with little to no differentiation between the two parameters (for example, Depp et al 2007); others have evaluated acceptability as a component of feasibility (for example, Horn et al 2008); and Sepulveda et al (2008) viewed feasibility as a part of acceptability. Therefore, since acceptability and feasibility are closely related, it is critical to consider how each of these parameters is defined for specific clinical contexts and to consider that they may have overlapping aspects.

Feasibility

The feasibility of an intervention is whether patients believe what is being asked of them is manageable and practical. It does not encompass the feasibility of conducting a study, which may involve recruiting participants and collecting and analysing data, but it may involve the delivery

method (for example, use of technology or devices) or intervention providers. Therefore, feasibility must be evaluated as a package.

Subjective measures, including self-reported concerns about the convenience or burden of the intervention, and objective measures, such as participation and attrition rates, have been used to capture feasibility.

For example, Steinberg et al (2016) examined a 'mindfulness' intervention (one that included meditation, yoga and music) designed to increase surgical intensive care unit staff members' resilience to daily stress. It used feasibility measures including attendance and retention rates, self-reports of frequency of practice sessions and use of an audio CD explaining the intervention, and subjective ratings of the relevance of the content and format of the intervention.

By comparison, Donovan et al (2016) examined the feasibility of a mindfulness and self-compassion mobile intervention by asking healthy adolescents to use a mobile app for 30 days, after which they would take part in a satisfaction survey and focus group.

Both of these studies recommended a follow-up study to test the interventions' efficacy or effectiveness (Donovan et al 2016, Steinberg et al 2016). However, before testing efficacy or effectiveness, examination of the fidelity of the intervention is important.

Fidelity

The fidelity of an intervention is the skilled delivery of the intervention according to a protocol (Zauszniewski 2012). Lack of fidelity may reflect a gap between the planned and the implemented protocol, and can affect internal and external validity and a study's outcomes (Bellg et al 2004, Durlak and Dupre 2008, McHugh et al 2009).

The five components of fidelity are (Duffy et al 2015, Bekhet 2017):

- Design – although a study's design is important, it may not directly affect intervention implementation.
- Training – this should be consistent across intervention providers.
- Delivery – the intervention provider should follow the prescribed protocol.
- Receipt – this reflects how well the intervention providers have learned the skills needed, as well as their confidence in providing the intervention.
- Enactment – this involves assessing the involvement of the recipients in the intervention.

Duffy et al (2015) assessed fidelity across seven studies of smoking cessation interventions for inpatient cigarette smokers. The researchers used checklists to ensure that each intervention component was addressed, as well as documentation by intervention counsellors, including the number and duration of counselling calls and the overall success in reaching participants.

French et al (2015) evaluated the fidelity of an interactive, face-to-face educational intervention in improving GPs' management of back pain. The researchers used audio recordings from intervention sessions, workshop transcripts to track the delivery of behaviour change techniques in relation to the

planned protocol, and checklists completed after each session; these were compared with a 'gold standard' using sensitivity and specificity analyses. However, neither of these two studies examined whether the recipients perceived the intervention to be physically or psychologically safe.

Safety

The safety of an intervention means that it does not cause intervention recipients physical harm or mental distress (Zauszniewski 2012).

As far back as the 1970s, guidance has been provided for the conduct of clinical trials that has included a data and safety monitoring board to oversee the studies (for example, by the National Institutes of Health).

There is continued emphasis by international review boards governing the protection of human study participants on the prevention of psychological and physical risks and adverse effects associated with interventions tested in clinical trials. This parameter therefore requires careful attention and examination during the development of interventions and pilot research.

Comeau et al (2015) examined an intervention to keep patients safe during intra-facility transport. The researchers used a checklist to evaluate the preparation of patients before transport, screening for criteria that may place patients at higher risk during transport and after transport.

Safety is not commonly evaluated in studies involving psychological interventions (Jonsson et al 2016, Zech et al 2017), but there is a need to monitor negative or adverse effects from psychotherapeutic interventions (Linden 2013, Naeem et al 2016).

Linden (2013) suggested the need to evaluate deterioration, adverse events, severe reactions, novel symptoms, attrition, non-responsiveness, unwanted or unanticipated responses, suicide attempts and deaths from unnatural means or causes. However, given technological advances and the use of the internet and social media to provide interventions, the need to monitor psychological discomfort during an intervention goes beyond observing recipients' non-verbal behaviour during the intervention or requesting their feedback afterwards (Zauszniewski 2012) and the factors identified by Linden (2013).

The use of mobile apps to provide interventions presents additional challenges (Naeem et al 2016), including safety concerns resulting from security and privacy issues (for example, personal identification), a particular intervention (for example, unintended responses), or digital technology (for example, internet addiction or inappropriate or inaccurate information is provided).

An important consideration is that it may be impossible to intervene with the recipient to ensure no serious psychological harm results from exposure to the intervention.

Once an intervention's physical and psychological safety is established, a logical next step is to examine its effectiveness.

Effectiveness

Effectiveness is determined using experimental designs, including a comparison of people who receive the intervention with people who do not (Whittemore and Grey 2002, Zauszniewski 2012).

Effectiveness must be distinguished from efficacy, which was not included in Zauszniewski's (2012) six original intervention parameters: effectiveness is based on clinical practice in the 'real world', which has a variety of unpredictable factors that cannot be strictly controlled (Gartlehner et al 2006), while efficacy is tested in strictly controlled conditions (Whittemore and Grey 2002). Therefore, effectiveness and efficacy are concepts that lie on the same conceptual spectrum but should not be used interchangeably.

Huang et al (2015) examined the effectiveness of an individualised treatment at reducing constipation among nursing home residents with an eight-week follow-up assessment. Measures of effectiveness included frequency of defecation and bowel sounds.

Benavent-Caballer et al (2016) examined the effectiveness of a video-supported, group-based exercise programme at improving the physical performance of community-dwelling older people without cognitive impairments. Measures of effectiveness included mobility, functional balance, one-leg balance and lower-extremity strength.

Both studies examined the effectiveness of the interventions in less controlled environments, which differentiated them from efficacy trials.

Efficacy

Efficacy is determined by comparing under strictly controlled conditions people who receive an intervention with people who do not (Whittemore and Grey 2002). Strictly controlled conditions may include laboratory settings and restrictions in sampling criteria.

Mezzasalma et al (2016) used a symptom questionnaire, a health-related quality of life questionnaire and faecal samples to examine a probiotic supplement's efficacy in alleviating symptoms of irritable bowel syndrome. Campbell et al (2016) investigated the efficacy of a computerised, home-based, cognitive rehabilitation intervention for people with multiple sclerosis; the researchers used neuropsychological and magnetic resonance imaging data at three time points at specialised facilities. However, these studies did not evaluate yet another important parameter – the cost of the intervention.

Cost

The cost of an intervention is how expensive it is to provide and perform the intervention, which typically includes the cost of training interventionists and recipients, equipment, time, incentives and other necessary resources. The Panel on Cost-Effectiveness in Health and Medicine published guidelines for analysing cost-effectiveness to standardise methods, reporting and resources, and to

assist with broad comparisons across interventions studied through randomised controlled trials (Sidora-Arcoleo and Frick 2012). Such guidelines are helpful to researchers designing interventions.

McInness et al (2014) assessed the cost of an intervention that sent appointment reminders to homeless veterans using text messages to try to decrease the number of cancelled and no-show appointments for primary care, specialty care, laboratory testing and other procedures. Cost analysis used an inflated average cost approach to estimate the savings if the intervention was applied to the entire Veterans Health Administration system. However, the analysis included only general and emergency visits; it did not include research assistant costs, as a future implementation would use a computer rather than a research assistant.

Oti et al (2016) tested an 18-month, community-based intervention to reduce cardiovascular disease by improving access to screening and treatment. The cost of the intervention was systematically determined by a review of financial records and interviews with staff. Cost was further described 'per unit of health gain', defined in terms of controlled blood pressure over time. Intervention costs were also evaluated, including those of staff, medication, travel, training, equipment, building operation and maintenance, transport, incentives for patients and indirect expenses such as overheads.

Conclusion and recommendations

When developing an intervention, it is essential to examine critical intervention parameters before testing it with a randomised controlled trial and using it in practice. We therefore propose a model consisting of eight intervention parameters and recommend that all of them should be evaluated and considered together. This new model adds two parameters – cost and efficacy – to Zauszniewski's (2012) six-parameter model, which has been implemented in recent research (Bekhet et al 2012, Musil et al 2015, Pinto et al 2016, Zauszniewski et al 2017). These studies examined all six parameters in the original model and provided comprehensive analysis of the interventions of interest, although few studies (for example, Appelhans et al 2013, Zauszniewski et al 2013, Theeke et al 2015, Bekhet 2017) have examined more than one parameter.

The importance of examining all the intervention parameters, including the two we have recommended, cannot be overlooked. Input from intervention providers, recipients, healthcare professionals and family is indispensable. All eight parameters, particularly effectiveness, should be evaluated in the clinical context in which the intervention will be provided: the effectiveness of an intervention may be irrelevant if it is viewed as unnecessary, unacceptable or unsafe (Zauszniewski 2012); without documented fidelity, efficacy or effectiveness in a particular clinical environment may be meaningless (Zauszniewski 2012); and if an intervention's cost is prohibitive, its efficacy or effectiveness may inconsequential. Therefore, simultaneous examination of all eight parameters is critical before developing, refining and testing the intervention in clinical trials and translating it into practice.