Evaluation and Program Planning 46 (2014) 58–71

Contents lists available at ScienceDirect

Evaluation and Program Planning

journal homepage: www.elsevier.com/locate/evalprogplan

A six-step protocol to systematic process evaluation of multicomponent cluster-randomised health promoting interventions illustrated by the Boost study

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ARTICLE INFO

Article history:
Received 30 August 2013
Received in revised form 5 May 2014
Accepted 14 May 2014
Available online 23 May 2014

Keywords:
Process evaluation
Multicomponent intervention
Adolescent
School
Dietary

ABSTRACT

Background: In multicomponent interventions it is important to examine the implementation of each component to enable valid assessments of the effectiveness of each component. Many studies do not systematically document, evaluate and report the level of implementation and there is a lack of systematic approaches to conduct process evaluation studies to guide researchers and evaluators.

The aim of this study was to present a systematic approach to plan process evaluation of the implementation of randomised multicomponent interventions.

Methods: Building on existing process evaluation frameworks and concepts, we developed a six-step protocol: 1. Brainstorm of processes necessary for full implementation and potential barriers and facilitators to implementation; 2. Application of process evaluation concepts to ensure inclusion of important implementation processes; 3. Measurement of proximal outcomes; 4. Identification of relevant data sources; 5. Selection of methods and timing of data collection of process measures; 6. Development of instruments. The protocol was applied to the Boost study, a multicomponent school-based dietary intervention.

Results and conclusions: The protocol was readily applicable for planning process evaluation of environmental and educational intervention components in a school setting. The protocol ensures systematic assessment of the implementation processes that are crucial for interpretation of intervention effects.

Trial registration: Current Controlled Trials ISRCTN11666034.

1. Background

Systematic reviews indicate that theory-based, multicomponent interventions are most effective in increasing fruit and vegetable (FV) intake among children and adolescents (Blanchette & Brug, 2005; Evans, Christian, Cleghorn, Greenwood, & Cade, 2012; French & Stables, 2003; Hoelscher, Evans, Parcel, & Kelder, 2002; Knai, Pomerleau, Lock, & McKee, 2006). However, multicomponent interventions are complex to evaluate and the separate effects and implementation of each single component are seldom reported (French & Stables, 2003). Furthermore, many studies do not systematically document or evaluate to what extent interventions were delivered and received (Armstrong et al., 2008; Linnan & Steckler, 2002). To enable the correct interpretation of intervention effects and refinement of intervention designs, it is important to evaluate which components are feasible to implement and which are effective, for whom and under which conditions (Linnan & Steckler, 2002).

Assessment of the implementation levels can reduce the risk of type III error. This error occurs when an intervention is deemed ineffective while in reality it is inadequate implementation that accounts for the lack of effect (Durlak, 1998; Durlak & DuPre, 2008). Few studies report whether activities similar to those included in the intervention programme took place in the control group. This is important to monitor in order to assess the influence from contamination bias and lack of exposure contrast on intervention effectiveness.

Process evaluation can be used to identify to what extent each component was implemented and, accordingly, whether it is

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http://dx.doi.org/10.1016/j.evalprogplan.2014.05.004
0149-7189/

plausible that the effect of the intervention could be ascribed to this particular component (Bartholomew, 2006; Linnan & Steckler, 2002). Many studies, including FV interventions, compare changes in determinants of distal outcomes (for FV intake e.g. changes in FV intake) in the intervention and control group without linking these changes to the implementation of specific intervention components (Baranowski & Jago, 2005; Durlak & DuPre, 2008; Krølner et al., 2012). The assessment of relations between process evaluation concepts and proximal and distal outcomes (determinants of FV intake and FV intake) needs to be developed (Baranowski & Stables, 2000).

Assessment of proximal outcomes is important as it can provide pathway information of the theory- and evidence-based link between implementation of specific intervention components and health behaviour change e.g. change in FV intake. This may clarify the effectiveness of single components on FV intake (Baranowski & Jago, 2005). For example, if change in FV intake is mediated by knowledge, it is plausible that this effect can be ascribed to curricular activities in a multicomponent intervention. If the effect is mediated by the variety of FV the pupils are exposed to at school, this may reflect the success of free FV provision.

Another important part of process evaluation is to assess social context and reach (Linnan & Steckler, 2002). Scholars emphasise that the constant effect assumption may not hold in cluster-randomised trials as contextual characteristics can vary greatly between clusters (Fuller & Potvin, 2012). For example, schools may differ according to pupil composition, economic resources, facilities and organisational climate. To assess the external validity of intervention effects, it is therefore important to study interactions between context and intervention components (Fuller & Potvin, 2012). Similarly, the reach and effectiveness of the intervention components may differ according to subgroup such as adolescents from high- and low-income homes (Oldroyd, Burns, Lucas, Haikerwal, & Waters, 2008). Lastly, studies of barriers and facilitators to implementation are needed to enable the design of more feasible interventions.

In the current literature, few systematic approaches to guide process evaluation efforts are available, and process evaluation concepts, such as fidelity and dose delivered, are defined inconsistently (Armstrong et al., 2008; Linnan & Steckler, 2002). Whereas guidelines exist for reporting of design, conduct, effect analysis, and interpretation of randomised controlled trials (CONSORT Statement 2012), there is no state-of-the-art approach to report process evaluation studies.

The conceptual framework of Baranowski and Stables (2000) lists eleven components of process evaluation. Building on these, Linnan and Steckler (2002) suggest and define various process evaluation concepts, such as 'dose' and 'fidelity', to be assessed in process evaluation studies, and they present a strategy for designing and implementing process evaluation efforts (Linnan & Steckler, 2002). Saunders, Evans, and Joshi (2005) have adapted these concepts and steps and present another approach to process evaluation (Saunders et al., 2005).

Process evaluation studies of previous interventions designed to increase children's intake of FV (Baranowski & Stables, 2000; Bere, Veierod, Bjelland, & Klepp, 2006; Bouck et al., 2011; Christian et al., 2012; Lien et al., 2010; Newell et al., 2004; Potter et al., 2011; Reynolds et al., 2000; Wind et al., 2008) have applied different approaches and have reported these with a different level of detail. This makes comparisons and summary across studies difficult. In several studies the theoretical framework of the process evaluation was not specified (Bere et al., 2006; Bouck et al., 2011; Christian et al., 2012; Newell et al., 2004; Potter et al., 2011; Reynolds et al., 2000; Wind et al., 2008). The studies assessed different process evaluation concepts. Moreover, the studies seem to use different concepts to describe similar aspects of process evaluation e.g. the 'quality' and 'fidelity' of the intervention are used synonymously to describe whether the intervention was implemented as originally planned (Lien et al., 2010; Newell et al., 2004).

The aim of this paper was to present a systematic approach to planning process evaluation of the implementation of multicomponent, cluster-randomised intervention studies using the Boost study as an example. The Boost study is a school-randomised controlled trial designed to increase FV intake among Danish 13-year-olds through a combination of educational and environmental strategies in three settings: school, home and local community.

2. Methods

Building on conceptual frameworks and process evaluation concepts defined by Baranowski and Stables (2000), Linnan and Steckler (2002) and Saunders et al. (2005), we developed a six-step protocol to plan process evaluation of multiple intervention components. The six steps are listed chronologically below. We used an iterative process to develop process evaluation plans for the different intervention components.

Step 1: Brainstorm of processes necessary for full implementation and potential barriers and facilitators to implementation
Step 2: Application of process evaluation concepts to ensure inclusion of important implementation processes
Step 3: Measurement of proximal outcomes
Step 4: Identification of relevant data sources
Step 5: Selection of methods and timing of data collection of process measures
Step 6: Development of instruments

2.1. Application of the six-step protocol – illustrated by the Boost study

2.1.1. The Boost study

The aim of the Boost study was to promote FV consumption among 13-year-olds (school year 7) by improving their access to FV at school, at home and during leisure-time activities. The development of the intervention, implementation and evaluation was guided by the Intervention Mapping protocol (Krølner et al., 2012; Bartholomew, 2006). Programme activities were implemented for nine months in the school year 2010/2011 (September 2010–May 2011). The programme combined environmental and educational strategies in three settings as listed below.

The Boost intervention was tested in a cluster-randomised controlled study design with 20 intervention and 20 control schools randomly selected from a random sample of 10 municipalities in Denmark (Krølner et al., 2012). Baseline, first and second follow-up questionnaire surveys were conducted in August 2010, May/June 2011 and May/June 2012, respectively. Trial registration: Current Controlled Trials ISRCTN11666034.

2.1.1.1. School components. Daily provision of free FV: teachers were to give pupils one piece of fruit or a vegetable daily during class. The cooperative owner of a chain of supermarkets partly financed the delivery of FV and appointed local supermarkets as FV suppliers to deliver the FV to the schools in the morning twice a week.

A pleasant eating environment: teachers were asked to implement an FV break during a lesson or a break, enabling the pupils to eat the delivered FV together. All classrooms were provided with utensils to prepare and serve the FV with the aim of creating a cosy eating atmosphere (see Box 1 for explanation of the notion *cosy*). The implementation manual suggested designating pupils as FV