Metodološki zvezki, Vol. 17, No. 2, 2020, 1–29

Quality guidelines for mixed methods research in intervention studies: A conceptual model

Gizela Kopač, Valentina Hlebec*

University of Ljubljana, Faculty of Social Sciences, Ljubljana, Slovenia

Abstract

Among researchers' many investigations of the use of mixed methods in intervention studies, more recent discussions especially concern the roles played in such studies by qualitative research, intervention phases, procedures, and integration (Gallo and Lee, 2016; Woolcock, 2018; O'Cathain, 2018; Creswell and Plano Clark, 2018). One can find the basic procedures to follow while realizing a mixed methods experimental design (Creswell and Plano Clark, 2018), practical guidance (O'Cathain, 2018) for using qualitative research with a randomized control trial (RCT), and a mixed methods appraisal tool for appraising the methodological quality of RCTs, non-randomized studies, and mixed methods – MMAT (Hong et al., 2018). However, no model exists to assess the quality of mixed methods research in intervention studies, particularly experimental and quasi-experimental research in complex interventions. Our aim is to develop such a theoretical model. Today, the number of interventions relying on mixed methods methodology is growing exponentially. A theoretical model is called for to help assess the quality of mixed methods research in intervention studies, and in this respect our aim is to: (1) provide an overview of guidelines, recommendations, models, and quality criteria for mixed methods research; (2) overview the guidelines for intervention studies; (3) give a summary of guidelines and models for mixed methods research in such studies; (4) evaluate the mentioned guidelines, models, and quality criteria; (5) identify and describe the key elements of these guidelines, models, and quality criteria; and (6) develop a theoretical model for assessing the quality of mixed methods research designs used in intervention studies.

1. Introduction

Mixed methods research has become a substantive and rising methodological force seeing ever greater popularity in all types of research, including intervention research (Creswell and Plano Clark, 2018). In this paper, we develop a universal model for the quality assessment of mixed methods research in intervention studies. We investigate relevant discussions about the value of mixed methods for intervention research. An overview of guidelines,

*Corresponding author

Email addresses: gizela.kopac@gmail.com (Gizela Kopač), valentina.hlebec@fdv.uni-lj.si (Valentina Hlebec)

recommendations, models, and quality criteria for mixed methods research and intervention studies is then provided. This is evaluated in terms of the components of these guidelines and models. The outcome of this evaluation is the construction of a conceptual model. The article is divided into three parts: (1) discussions on the value of mixed methods in intervention research; (2) an overview and evaluation of guidelines, recommendations, models, and quality criteria for mixed methods research and intervention studies; and (3) the construction of a conceptual model to assess the quality of mixed methods research in intervention studies.

The investigation of mixed methods research in intervention studies is in fact not new. Many authors have considered the value of mixed methods for intervention research. Discussions led by Sandelowski (1996), Lewin et al. (2009), O'Cathain et al. (2013), Drabble and O'Cathain (2015), and Grissmer (2016) focused on a combination of a qualitative approach and RCTs. Margatete Sandelowski (1996) looked at how the qualitative component can be included and applied in RCTs to understand how RCT findings may be applied in a real-word clinical setting. Similarly, Lewin et al. (2009) examined the use of qualitative methods in association with RCTs of complex healthcare interventions while O'Cathain et al. (2013) also concentrated on the relationship between qualitative research and RCTs, where 296 articles in which qualitative research and RCT were used were identified. On the other hand, Drabble and O'Cathain (2015) explored the value of mixed methods intervention evaluations in RCTs to understand an intervention's effectiveness. Finally, Grissmer (2016) explored the purpose of mixed methods in educational and social interventions where RCTs are used and found that mixed methods are powerful tools when coupled with an RCT to understand why the effects of an intervention occurred (or not), how, and why they vary among the participants.

Other authors like Protheroe et al. (2008), Song et al. (2010), Farquhar et al. (2011), Bamberger (2012), Hesse-Biber (2012), Farquhar et al. (2013), Boeije et al. (2015), Brown et al. (2015), Jimenez et al. (2018), Woolcock (2018), and Palinkas et al. (2019) concentrated more on the contribution of mixed methods to different intervention and evaluation phases. For example, Protheroe et al. (2008) investigated the benefits of mixed methods for evaluating a complex intervention and emphasized possible discrepancies in quantitative and qualitative results. Meanwhile, Song et al. (2010) looked at how mixed methods intervention studies were conducted in the health sciences before developing the following components of mixed methods intervention research programs: developing the intervention research program's theoretical foundation; the pilot test of the efficacy, feasibility, acceptability, treatment conditions, and measurements of the outcomes; assessing the intervention efficacy, and testing the intervention's effectiveness. Farquhar et al. (2011) examined how and why mixed methods are used to develop and evaluate complex interventions in palliative care. Use of the mixed methods approach was explained by Bamberger (2012) in an impact evaluation together with its essential elements, while also presenting the design of a mixed methods impact evaluation in the context of complex interventions. Hesse-Biber (2012) introduced the value of mixed methods research to assess the effectiveness of clinical interventions or which specific interventions are best suited for adoption in a research trial within clinical settings.

Investigating the use of mixed methods approaches as part of complex intervention development and evaluation (Farquhar et al., 2013) as well as identifying the methodological challenges of mixed methods intervention evaluations in complex interventions (Boeije et al., 2015) and the role of mixed methods in the effectiveness, acceptability, feasibility, and implementation of both the intervention and evaluation study (Boeije et al., 2015) have be-

come important aspects of the scholarly enquiry into the value of mixed methods research in intervention studies. In the same year, Brown et al. (2015) explored the environments in which health interventions occur, investigated the evaluation of interventions, and ascertained that the role of mixed methods in such evaluations is to consider the intervention's content and context. There were also investigations about the roles of mixing, matching, and the use of qualitative methods to improve quantitative impact evaluations (Jimenez, 2018) and the importance of qualitative methods in complex intervention evaluations (Woolcock, 2018). In 2019, Palinkas et al. (2019) found that mixed methods designs had become ever more common in healthcare for evaluating the process and outcomes of an intervention, program, or policy effectiveness and investigated how mixed methods have been used in healthcare interventions.

In addition, Protheroe et al. (2008), Lewin et al. (2009), Farquhar et al. (2011), Farquhar et al. (2013), and Noyes et al. (2019) delved into the value of mixed methods in complex interventions. While in 2009 Lewin et al. (2009) looked more at the use of qualitative methods alongside randomized controlled trials in complex healthcare interventions, in 2011 Farquhar et al. investigated the development and evaluation of complex interventions in palliative care. Noyes et al. (2019) determined that mixed methods hold the potential to increase understanding of how complex interventions work, for whom, and how complex health systems respond and adapt. Albright et al. (2013) also considered the use of mixed methods in intervention research and established that one benefit of mixed methods is that it includes both quantitative methods to examine the intervention content (the 'what') and qualitative methods for exploring the context (the 'why' and 'how').

Creswell and Plano Clark (2007) studied the use of mixed methods in intervention research, calling this design an "embedded design", whereby the researcher must embed a qualitative component into a quantitative design, like in an experimental design. They presented an "embedded experimental model", a variant of the embedded design that is the variant of this design most commonly relied on. This model embeds qualitative data within an experimental design (such as a true experiment or quasi-experiment) with the data collection process occurring before, during, or after the intervention. In 2011, Creswell and Plano Clark renamed it an "embedded experimental mixed methods design". They presented the procedures for preparing an embedded design: (1) designing the overall experiment and deciding on why qualitative data need to be included; (2) collecting and analyzing qualitative data to enhance the experimental design: (3) collecting and analyzing quantitative outcome data for the experimental groups; and (4) interpreting how the qualitative results enhanced the experimental procedures and/or understanding of the experimental outcomes. Creswell (2015) relabeled this design an "experimental intervention design" in which the investigator gathers qualitative data in some phase during the experiment, either before, during, or after the trial. Integration consists of embedding the qualitative data into the experimental design. Finally, in 2018, Creswell and Plano Clark conceptualized this type of design as a "mixed methods experimental (intervention) design" that constitutes one of the complex mixed methods designs.

2. Guidelines, recommendations, and models for mixed methods

The researcher is informed by guidelines, recommendations, and models in the research process regarding how something should be done. They are a structured tool for researchers to rely on while conducting or reporting the research process. Different study types have their own guidelines for conducting or reporting the research process. The mixed methods research process lacks methodological rigor in intervention studies. Researchers need

transparent and clear information on how to use mixed methods methodology in intervention research. We introduce guidelines, recommendations, and models which can be found in relevant mixed methods literature. We divide them into three groups: (1) general guidelines; (2) guidelines in specific disciplines; and (3) guidelines in health, psychological, educational, and evaluation-focused associations. Our aim is to consider the individual components of these guidelines, recommendations, and models before building our conceptual model.

2.1. General guidelines, recommendations, and models for mixed methods research

Many discussions about mixed methods research can be found with respect to guidelines, recommendations, and models. While Onwuegbuzie and Teddlie (2003) described and illustrated seven stages of the mixed data analysis process: data reduction, data display, data transformation, data correlation, data consolidation, data comparison, and data integration, Maxwell and Loomis (2003) and Maxwell (2012) presented an interactive model of research design consisting of: purposes, conceptual framework, research questions, research methods (sampling, data collection, data analysis), and validity. They attempted to show the value of this interactive research design concept for understanding mixed methods research. Tashakkori and Teddlie (1998) discussed mixed methodology, examined sampling issues, data collection procedures and data analysis techniques, and considered ways to utilize mixed approaches. The authors explored the criteria a researcher can rely on for a mixed methods design (Tashakkori and Teddlie, 2010) and mixed methods research questions, sampling issues in mixed methods research, along with the analysis of mixed methods data and integration (Tashakkori and Teddlie, 2009).

The framework for sampling designs in mixed methods research, along the way describing sampling schemes and discussing sample size, was presented by Onwuegbuzie and Collins (2007). They listed four possibilities: identical sampling, parallel sampling, nested sampling, and multilevel sampling. Specific guidelines for practice as one of the methodological domains include: purpose, mixed methods questions, data analysis (integrated analysis, joint and interactive analysis), and integrated mixed methods analysis strategies (data transformation and data comparison) (Greene, 2008). Leech (2012) described how researchers have little guidance when it comes to writing up a mixed methods research study and thus offered recommendations for such an endeavor, including: purpose/rationale, research questions, the mixed methods design, and the integration. Guest (2012) presented a list of six descriptive dimensions for mixed methods research: timing of the interface, purpose of the interface, theoretical orientation, purpose of the research, number of points of interface or degree of integration, as well as the relative importance of qualitative data vs. quantitative data (weighting). He stressed that while every dimension is important for a study's conceptualization, the timing and purpose of the integration are crucial with respect to describing a study.

Guest and Fleming (2014) outlined some of the most common mixed method design typologies and stressed the importance of three dimensions: timing, purpose, weighting. They presented general guidance in the design of a mixed methods study and a simple set of instructions on the basic steps: the research question/problem, justification for the mixed methods research, data collection and analysis, mixed methods design, and data integration. On the other hand, Fetters and Freshwater (2015) presented an hourglass model of mixed methods research. At the top of the hourglass model one finds the broader methodological context, the purpose of the mixed methods, and the research questions. In the middle of model lies the mixed methods design, sampling, measurement procedures, data analysis, data integration, and software applications. At the bottom of this model there are: a dis-

cussion of the mixed methods integration, field-specific implications, and methodological implications for mixed methods. The authors conclude that integration is a challenge and that guidance exists to assist integration.

Creswell (2015) discusses six steps in designing a mixed methods study: (1) the research question; (2) types of data collection and analysis; (3) the reasons for using mixed methods; (4) diagrams, procedures, and choice of design; (5) the mixed method study's aim or purpose; and (6) the quantitative, qualitative, and mixed methods questions. He also introduces a checklist of elements to include during a mixed methods manuscript preparation: the type of mixed methods design, the rationale, the mixed methods study's aim and purpose, the quantitative, qualitative, and mixed methods research questions, the quantitative and qualitative data collection and analysis, and the integration of quantitative and qualitative data. While Graff (2017) looks at the emergence, purpose, and characteristics of mixed methods research and identifies the following characteristics: mixed methods designs, research questions, sampling, data collection, data analysis, mixing qualitative and quantitative phases, and a detailed discussion of purposive probability sampling techniques, Schoonenboom and Burke Johnson (2017) show how to design a high-quality mixed methods research study, proposing seven major design dimensions: purpose, theoretical drive, timing (simultaneity and dependency), point of integration, typological vs. interactive design approaches, planned vs. emergent design, and design complexity. They also propose multiple secondary dimensions. The authors believe the most important decision in mixed methods research is to determine the point(s) of integration and how the results are to be integrated.

Creswell and Plano Clark (2018) consider how to design and conduct mixed methods research and list the following steps: (1) research problem; (2) research purpose; (3) research question; (4) rationale; (5) collecting qualitative and quantitative data; (6) sampling procedures/site(s); (7) participants; (8) sample size; (9) participant recruitment; (10) data sources identification; (11) data analysis (statistical software); and (12) integration. They highlight the crucial steps and describe them in detail. They outline three core mixed methods designs (convergent, explanatory sequential, exploratory sequential) and four prominent types of complex mixed methods designs (mixed methods experimental (intervention), mixed methods case study, mixed methods participatory-social justice, mixed methods program evaluation).

2.2. Guidelines, recommendations, and models for mixed methods research in specific disciplines

Many authors have presented guidelines, recommendations, and models for a specific discipline. Creswell, Fetters, and Ivankova (2004) established the criteria for analyzing mixed methods studies in primary care research and then used them to evaluate mixed methods investigations in primary care research journals. They identified the following study characteristics: content area, rationale for mixing, forms of data collection (quantitative/qualitative), analytical procedure (quantitative/qualitative), characteristics of the design (priority, implementation), integration, and type of design model. They concluded these characteristics are rigorous elements which primary care investigators may rely on while designing their studies. On the other hand, Collins, Onwuegbuzie, and Sutton (2006) created a framework for conducting mixed research studies called the RAP model – a 13-step model for conducting mixed methods research in special education and beyond, divided into three stages: research formulation, research planning, and research implementation. Research formulation entails the: (1) mixed goal of the study; (2) mixed research objective; (3) rationale for mixing; (4) purpose of mixing; and (5) mixed research question(s). Research

planning involves: (1) the mixed sampling design; (2) the mixed research design; (3) collecting quantitative and qualitative data; and (4) analyzing quantitative and qualitative data, namely quantitative and qualitative analysis techniques. Research formulations consist of: (1) validating the mixed research findings; (2) interpreting the findings; (3) writing up the mixed research report; and (4) reformulating the mixed research question(s).

GRAMMS – the Good Reporting of a Mixed Methods Study checklist was developed for health services research (O'Cathain, Murphy, and Nicholl, 2008). Their study analyzed research reports of 75 health services in England between 1994 and 2004, with the analysis leading the study to produce the GRAMMS framework. This six-item framework contains: a justification for using mixed methods, the design (purpose, priority, sequence of methods), a description of each method (sampling, data collection, analysis), where and how integration occurred, the limitation of each method, and insights from the mixing or integrating of methods. Schifferdecker and Reed (2009) investigated the application of mixed methods in medical education research. They outlined the main steps in designing, analyzing, and publishing: identify the study design; decide on the prominence of each data type in the data collection, analysis, and results; develop sampling strategies for the data collection; decide how and when data are to be collected, analyzed, integrated, or compared; explore tools (software programs) or methods to integrate the quantitative and qualitative data; and review mixed methods research articles. Leech and Onwuegbuzie (2010) examined the application of mixed methods in the counseling field and beyond and detected a dearth of mixed research studies in the related literature. They proposed several guidelines: sample size, sample information, the sampling scheme for the quantitative/qualitative research, the sampling scheme for the mixed methods research, the type of generalization, the mixed research design, the quantitative research design, and the qualitative research design.

Mixed methods research has also been introduced as a relevant approach to music therapy practice containing core characteristics, recommendations, and key components: data collection and analysis of qualitative and quantitative data, design (RCT, ethnography), recruitment, sampling, and integration (Bradt, Burns, and Creswell, 2013). Venkatesh, Brown, and Bala (2013) reviewed the current state of mixed methods research while also investigating the value and purpose of mixed methods and providing guidelines for conducting mixed methods research in the area of information systems. These guidelines include several elements: purpose, design, data analysis, integration, and meta-inferences.

Onwuegbuzzie and Corrigan (2014) considered the value of mixed research studies in human resource development and analyzed empirical articles. They list evidence-based guidelines for conducting and reporting mixed research that are based on Collins, Onwuegbuzie, and Sutton's (2006) 13-step model, with the guidelines being divided into four domains: research formulation, research planning, research implementation, and research dissemination. These elements entailed are: determine the mixing rationale, establish the mixed purposes, present mixed research questions, select the sampling design, specify the type of sampling scheme, outline the mixed research design, collect data, analyze the data, and create the mixed data analysis strategy.

On the other hand, Wisdom, Cavaleri, Onwuegbuzie, and Green (2012) described the frequency of mixed methods in published health services research and concluded that such research provides a more comprehensive picture of health services than either method alone. They established that researchers who use mixed methods should follow rigorous methodologies. They created a list of mixed methods methodological components of health services research: integration of qualitative and quantitative components, a specified sequence of methods, areas of consistency between the methods stated, areas of inconsistency between

the methods stated, the stage of integration specified, priority of the methods specified, the stated purpose of mixing methods, and a statement on the limitations of the mixed methods. Venkatesh (2016) proposed the latest guidelines for conducting mixed methods research in the information systems field. He developed a model of decision choice for conducting mixed methods research which contains these elements: research question, purpose of mixed methods research, mixed methods design, sampling design strategies, quantitative/qualitative data collection techniques, mixed methods analysis, integration, meta-inferences, and assessing the quality of meta-inferences.

In terms of sampling, Onwuegbuzie and Collins (2007) focused more on a model for choosing samples for mixed research (identical sampling, parallel sampling, nested sampling, multilevel sampling), whereas Leech and Onwuegbuzie (2010) gave a detailed description of sampling (sample size, sample information, sampling scheme for quantitative/-qualitative research, the sampling scheme for mixed methods research). The guidelines for music therapy research of Bradt et al. (2013) also include recruitment as an important element. Wisdom et al. (2012) in guidelines for health services research stressed the importance of integration and suggested: the integration of qualitative and quantitative components, stating the areas of both consistency and inconsistency among the methods, while specifying the stage of integration, the priority of methods, and purpose of mixing. Guidelines for mixed methods in information systems (Venkatesh 2016) also include assessing the quality of meta-inferences.

2.3. Guidelines, recommendations, and models for mixed methods research in associations

Mixed methods guidelines, recommendations, and models have also been developed by various health, psychological, educational, and evaluation-focused associations. The U. S. National Institute of Health (2018) examined criteria for the design and evaluation of mixed methods research, proposing three already mentioned guidelines (Creswell and Plano Clark, 2018; O'Cathain, Murphy, and Nicholl, 2008; Schiffendecker and Reed, 2008). Creswell and Plano Clark (2018) stressed the importance of: research purpose, research question, collecting qualitative and quantitative data, sampling procedures/site(s), participants, sample size, recruitment, data sources, data analysis (statistical software), and integration. O'Cathain, Murphy, and Nicoll (2008) highlighted the importance of: the justification for using mixed methods, the design, a description of each method (sampling, data collection, analysis), where and how integration occurred, the limitation of each method, and insights from the mixing/integrating of methods. Schifferdecker and Reed (2008) emphasized the value of: the study design, prominence of each data type in the data collection, analysis, and results, sampling strategies, how and when data are collected, and the software programming tools or methods for integrating the quantitative and qualitative data.

Levitt et al. (2018) as a team at the American Psychological Association developed MMARS – Mixed Methods Article Reporting Standards. These standards were developed for the psychology field and contain: the mixed methods' objective, aim, and goal, the type of mixed methods design, the participants or other data sources; separate descriptions of samples if they vary; participant recruitment; participant sampling or selection; data collection; recording and transforming the data; data analysis, and integration/mixing.

Jalongo and Saracho (2016) investigated the use of mixed methods in education research and found that researchers should carefully consider the best way to write their report to ensure that it includes all necessary information. They designed guidelines for reporting a mixed methods study in education research with these components: state the research question(s), both quantitative and qualitative; assess the appropriateness of using mixed methods

research given the study's purposes; choose a specific mixed methods research design and supply the rationale for that choice; gather both quantitative and qualitative data; analyze the quantitative data with the appropriate statistical test and analyze the qualitative data using the most suitable qualitative analysis; interpret the data from a quantitative, qualitative, and blended perspective; legitimize the data by demonstrating how it simultaneously meets quantitative and qualitative criteria for quality; and make conclusions that emanate from the insights afforded by the mixed methods approach.

The American Evaluation Association (Glover-Kudon, 2010) introduced steps involved in the rationale and purpose of mixed-methods research, data prioritization, implementation sequence, data integration, strengths, and challenges. All four of the mentioned associations stress the importance of the: purpose/justification, research question, mixed methods design, sampling, methods (data collection and data analysis), and integration. A detailed description of sampling is given by the American Psychological Association and the American Educational Research Association.

These three groups of guidelines, recommendations, and models permitted an insight into the options researchers have available when relying on mixed methods methodology. We also obtained a list of components that make up these guidelines. Some components repeat, but in the sections below we look in detail and extract components of relevance to our concept model.

3. Quality criteria for mixed methods

Quality is a recent theme in mixed methods literature. Tashakkori and Teddlie (2009) stated that high-quality quantitative and qualitative components are necessary but not sufficient for a quality mixed methods study. The question is whether there should be separate quality appraisal criteria for quantitative and qualitative methods or mixed methods criteria (O'Cathain, 2010). Ivankova (2014) concluded that, although many mixed methods quality frameworks exist, there are no agreed criteria for evaluating mixed methods studies. Doyle et al. (2016) determined that quality appraisal is a more common topic in debates of recent times on the development of mixed methods and established that attention is focused on data analysis, integration, and quality appraisal. Fabregues and Molina-Azorin (2017) stated that quality is one of the most strongly debated topics in recent mixed methods literature and that a growing number of authors is interested in conceptualizing and operationalizing the quality of mixed methods research. These authors suggest that mixed methods research should be appraised according to its own set of quality criteria given that it has a number of features that distinguish it from single-method research.

Several researchers have proposed quality criteria to assess the quality of mixed methods (O'Cathain, 2008; Bryman, 2014; Creamer, 2018; Hong et al., 2018). For example, O'Cathain et al. (2008) devised a quality assessment framework consisting of six individual components, each entailing the assessment: of studies' success, of the studies' mixed methods designs, of the quantitative component of mixed methods studies, of the qualitative component of mixed methods studies, of integration in mixed methods studies, and of the inferences established in completed reports of mixed methods studies. Each of these six assessments is composed of quality questions offering the options "yes", "yes, but improvements are possible", "no", "not enough information", and "not applicable".

- Assessment of the success of mixed methods studies entails the following questions: "Is the quantitative component feasible?", "Is the qualitative component feasible?", "Have both the qualitative and quantitative components been completed?", "Is the

mixed methods design feasible?", "Were some qualitative methods planned but not executed?", "Were some qualitative methods planned but not executed?", and "Did the mixed methods design work in practice?".

- Assessment of the mixed methods design of studies contains the following questions: "Is the use of mixed methods research justified?", "Is the design for mixing methods described?" "Priority? Purpose? Sequence? Stage of integration?", "Is the design clearly communicated?", "Is the design appropriate for addressing the research questions?", and "Has the design's rigor been considered (proposal) or adhered to (report)?".

- Assessment of the quantitative and qualitative component of mixed methods studies attracts the following questions: "Is the role of each method clear?", "Is each method described in sufficient detail?", "Is each method appropriate for addressing the research question?", "Is the approach to the sampling and analysis appropriate for its purpose?", "Is there expertise among the applicants/authors?", "Is there expertise on the team to undertake each method?", "Have issues of validity been addressed for each method?", "Has the rigor of any method been compromised?", "Is each method sufficiently developed for its purpose?", and "Is the (intended) analysis sufficiently sophisticated?".

- Assessment of integration in mixed methods studies raises the following questions: "Is the type of integration stated?", "Is the type of integration appropriate to the design?", "Has enough time been allocated for the integration?", "Is the approach to the integration detailed in terms of working together as a team?", "Does the dissemination strategy detail how the mixed methods will be reported in final reports and peer-reviewed publications?", "Are the personnel who are to participate in the integration clearly identified?", "Did appropriate members of the team participate in the integration?", "Is there evidence of communication within the team?", and "Has rigor been compromised by the process of integration?".

- Assessment of the inferences made in completed reports of mixed methods studies brings the following questions: "Is there clarity about which results have emerged from which methods?", "Are the inferences appropriate?", and "Are the results of all the methods considered sufficiently in the interpretation?".

Bryman (2014) determined that most quality frameworks are too large and overly complex and therefore presented his own list of six core criteria for assessing the quality of mixed methods research, namely: implementation of the quantitative and qualitative components of the mixed methods project in a technically competent manner; transparency; the link of the mixed methods to the research questions; being explicit about the nature of the mixed methods design employed; and a rationale for the use of the mixed methods research and integration. Bryman's criteria are comparable with the components of the guidelines for mixed methods and O'Cathain's framework for a quality assessment. Both Bryman and O'Cathain expose the quantitative and qualitative components, the mixed methods design, and the integration. In our conceptual model, we shall include five quality criteria taken from Bryman: quantitative and qualitative components, research questions, mixed methods design, rationale, and integration.

Elisabeth Creamer (2018) described criteria for the mixed methods evaluation rubric (MMER) and emphasized the importance of identifying and explaining any inconsistencies

between the qualitative and quantitative data and the need to explain any inferences (Table 1). She distinguishes "framework" and "rubric" and concludes that they are both used for evaluation quality and both specify criteria for evaluating quality. However, a rubric uses numbers and establishes levels of quality. On the other side, a framework does not specify levels of quality, is typically dichotomous, and used for evaluating the presence or absence of a criterion.

Table 1: The criteria for mixed methods evaluation rubric (Creamer, 2018)

Evaluation criteria	0	1	2	3
Rationale for using mixed methods	No rationale	Rationale with no citations	Rationale with any citations	Rationale with citations from mixed methods literature
Research questions	No research questions	General research question(s)	At least one quantitative and one qualitative research question	Specific mixed method research question
Phases of mixing	No mixing	Mixing in one phase only	Mixing in two phases	Mixing in three or more phases
Degree of comparisons	No comparison	Mention comparison, but no evidence of comparison	Comparison for similarities only	Comparison for similarities and differences

Hong et al. (2018) conceptualized a critical appraisal tool for assessing the methodological quality of mixed methods studies and proposed the following methodological quality criteria: (1) Is there an adequate rationale for the mixed methods design to address the research question?; (2) Are the different components of the study effectively integrated so as to answer the research question?; (3) Are the outputs of the integration of the qualitative and quantitative components adequately interpreted?; (4) Are the divergences and inconsistencies between quantitative and qualitative results adequately addressed?; and 5) Do the different components of the study adhere to the quality criteria of each tradition of the methods involved? Possible responses were: "Yes", "No", "Can't tell", and "Comments". In our conceptual model, we shall rely on all five methodological quality criteria: rationale, integration, interpretation of outputs of the integration, divergencies and inconsistencies, and adherence to the quality criteria.

These four groups of quality criteria provided us with an insight into different quality criteria in mixed methods methodology. We also obtained a list of the components that make up these quality criteria. Some components repeat. We shall look in detail at where various quality criteria overlap and extract components of relevance to our conceptual model.

4. Guidelines for intervention studies

Interventions are treatments or strategies for improving outcomes and making a difference (Mazurek Melnyk and Morrison-Beedy, 2012). Experimental research is the type of research that allows conclusions to be made on whether cause-and-effect relationships exist between an intervention or treatment and an outcome. A randomized controlled trial is a type of experimental design that requires three components: an intervention or treatment, a comparison or control group, and the random assignment of participants to experimental or comparison/control groups (Mazurek Melnyk and Morrison-Beedy, 2012). A quasi experiment is a study in which the independent variable is manipulated, but where there is a lack of at least one of the other two properties of a true experiment (i.e., random assignment or a comparison/control group) (Mazurek Melnyk and Morrison-Beedy, 2012).

Several researchers have proposed guidelines for intervention studies. Schulz et al. (2010) developed the Consolidated Standards of Reporting Trials – CONSORT – which is a guideline for randomized trials. CONSORT contains 25 checklist items. It provides guidance for reporting all randomized controlled trials, although its aim is to provide guidance for individually randomized, two-group, parallel trials; namely, the most common design type. The CONSORT checklist is divided into five topics:

- introduction – background and objectives;
- methods – trial design, participants, interventions, outcomes, sample size, randomization, allocation, implementation, blinding, statistical methods;
- results – participant flow, recruitment, baseline data, numbers analyzed, outcomes and estimation;
- discussion – limitations, generalizability, interpretation; and
- other information.

Hoffmann et al. (2014) proposed the Template for Intervention Description and Replication – TIDieR. The TIDieR checklist's purpose is to encourage authors to describe interventions in sufficient detail to enable their replication. The checklist is composed of recommended items to use while describing an intervention. According to the authors, most TIDieR items are relevant for most interventions and applicable to every simple intervention. The TIDieR checklist contains 12 items:

- brief name: provide the name or a phrase that describes the intervention;
- why: describe any rationale, theory, or goal of the elements essential to the intervention;
- what (materials): describe any physical or informational materials used in the intervention;
- what (procedures): describe each procedure, activity, and/or process used in the intervention;
- who provided: for each category of intervention provider;
- how: describe the modes of delivery;

- where: describe the type(s) of location(s) where the intervention occurred;
- when and how much: describe the number of times the intervention was delivered and over what period of time;
- tailoring: if the intervention was planned to be personalized;
- modifications: if the intervention was modified during the course of the study;
- how well (planned): if intervention adherence or fidelity was assessed; and
- how well (actual): if intervention adherence or fidelity was assessed.

On the other side, Borek et al. (2015) suggested GB-BCIs – a checklist to improve the reporting of group-based behavior-change interventions, which also acts as a guideline for intervention research. Borek et al. (2015) developed a checklist of elements for the adequate reporting of GB-BCIs. The checklist consists of 26 essential elements that cover the intervention design, intervention content, participants, and facilitators.

Besides the MMAT critical appraisal tool for appraising the methodological quality of mixed methods studies (described in Section 3), Hong developed an appraisal tool for assessing randomized controlled trials and non-randomized studies. Possible responses are the same as for mixed methods studies: "Yes", "No", "Can't tell", and "Comments".

- For randomized controlled trials, the authors propose five methodological quality criteria: Was the randomization performed appropriately?; Are the groups comparable at the baseline?; Are there complete outcome data?; Are the outcome assessors blinded to the intervention provided?; Did the participants adhere to the assigned intervention?
- For appraising the methodological quality of non-randomized studies, the authors propose five methodological quality criteria: Are the participants representative of the target population?; Are the measurements appropriate regarding both the outcome and intervention (or exposure)?; Are there complete outcome data?; Are the confounders accounted for in the design and analysis?; During the study period, was the intervention administered (or exposed occurred) as intended?

All checklists, templates, and critical appraisal tools for intervention studies are important for our conceptual model. In the next sections we consider where elements of these checklists, templates, and appraisal tools repeat and overlap and then extract elements for the conceptual model.

5. Guidelines and models for mixed methods research in intervention studies

In recent years, authors have investigated the use of mixed methods in intervention research. They have proposed basic procedures while implementing a mixed methods experimental design (Creswell and Plano Clark, 2018) and practical guidance for using qualitative research with an RCT (O'Cathain, 2018).

Creswell and Plano Clark (2018) conceptualized basic procedures in realizing a mixed methods experimental design that can be divided into three steps: determine how the qualitative data will be used in the experiment; conduct the quantitative experiment, and establish how the qualitative findings enhance the experiment. In the first step of establishing how the qualitative data are to be used in the experiment, the researcher ascertains why qualitative

information is needed, how it will be used and whether the qualitative data will be collected before, during, or after the intervention (or in all three phases). In the second step of the quantitative experiment, the researcher specifies the conceptual model guiding the design, assigns participants to the experimental and control groups, designs and implements the experimental treatment, measures the outcome variables, analyzes the quantitative data using descriptive statistics, inferential statistics, and effect sizes to answer the quantitative research questions, collects and analyzes the qualitative data where it was placed in the experiment to answer the qualitative research questions, and undertake procedures to integrate the quantitative and qualitative results based on the reason for including the qualitative data. In the third step of establishing how the qualitative findings enhance the experiment, the researcher gives specific evidence of use of the qualitative findings and interprets how the qualitative findings enhance the experiment.

The basic procedures presented by Creswell and Plano Clark are valuable for our conceptual model. We will include: the rationale for using qualitative research, measurement of qualitative and quantitative methods (time of measurement), participants (assignment to experimental and control groups), collection and analysis of qualitative and quantitative methods, and integration. The authors introduced basic procedures for experimental designs generally without providing specific instructions for an experimental design and any instructions on how to construct mixed methods in experimental designs. There are no procedures to guide how to use mixed methods in quasi-experimental designs. Interventions can be very complex and the authors suggested general guidelines on how to use qualitative methods in experimental designs, yet they do not consider that some interventions may be very complex.

O'Cathain (2018) identified seven practical guidelines for using qualitative research with an RCT: the rationale for the qualitative research, research questions, methods of data collection, participants, sampling, analysis, and integration with the RCT. Rationale means describing why the qualitative research will add value to the RCT (O'Cathain, 2018). The research question is used to guide the application of the qualitative research in feasibility studies. O'Cathain (2018) suggests that the author should consider a broad range of questions, prioritize the initial questions, and allow for the possibility of new questions to emerge. The author focuses on research questions addressed by qualitative research. O'Cathain (2018) concludes that researchers employ different data collection methods as included along with RCTs. The author states that researchers often use methods in combination and that the selection of methods depends on the research questions. Regarding participants, O'Cathain stated that who is included in the data collection depends on the research question, intervention, context, and available resources. With respect to sampling, the author explored which type of sampling is employed and found that purposive sampling and maximum variation sampling are commonly used and that the type of RCT can influence the sampling. Sampling exists of participants, groups, sites, and stage of intervention. O'Cathain (2018) stated that the number of people included in qualitative research depends on the phase of evaluation, the aims of the qualitative research, the size of the RCT, data saturation, and the available resources. Many approaches to analyzing qualitative data with RCTs are mentioned by O'Cathain (thematic analysis, iterative approach, interpretative phenomenological analysis, content analysis). Further, O'Cathain (2018) mentioned integration in a phased sequential design and integration in a single-phase concurrent design and reviewed three integration techniques: integrating findings using an adapted triangulation protocol, working between the findings and the data sets by 'following the thread/s' and combining data using a mixed methods matrix. In our conceptual model, we shall include all seven of O'Cathain's

practical guidelines: rationale for the qualitative research, research questions, methods of data collection, participants, sampling, analysis, and integration with the RCT.

6. Development of the conceptual model

In this section, we describe the process of designing the conceptual model (Figure 1). We start with an overview of all elements forming part of the guidelines, recommendations, and models described in previous sections. The second step is to examine where the current guidelines and models overlap and to extract the most frequent elements. At the end, we use the elements extracted in our model. The conceptual model for assessing the quality of mixed methods in intervention research consists of elements found in guidelines, recommendations, and models for mixed methods, quality criteria for mixed methods, guidelines for intervention studies, and basic procedures and practical guidance for qualitative research and experimental design (RCT). From each guideline, recommendation, model, and quality criterion included, we extracted criteria for designing, reporting, or assessing mixed methods and intervention studies.

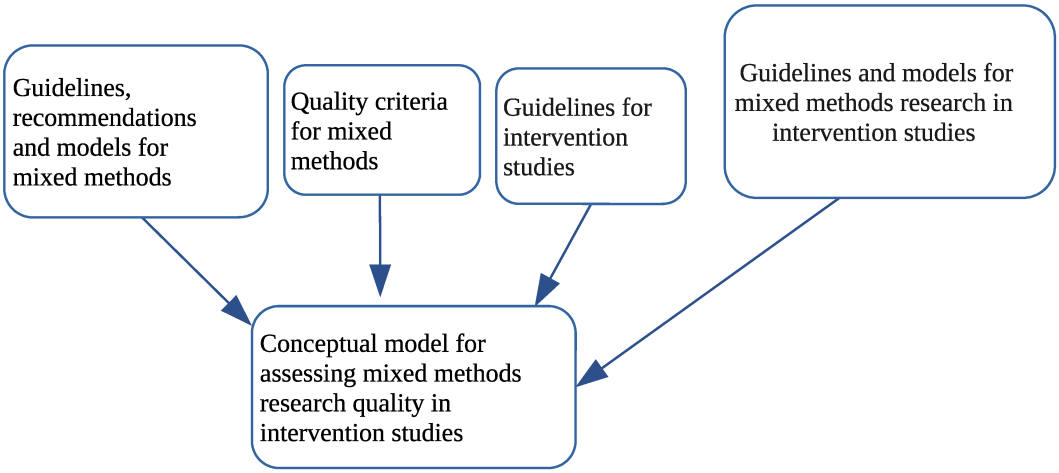

Figure 1: Conceptual model – development

6.1. Overview of items from guidelines, recommendations, models, and quality criteria

In sections two, three, and four, we overviewed 28 guidelines, recommendations, and models for mixed methods research, 4 quality criteria for mixed methods research and 4 guidelines for intervention studies. Some guidelines are general, while others focus on a specific mixed methods component: the purpose for mixing (triangulation, complementarity, development, initiation, expansion); mixed methods sampling (identical sampling, parallel sampling, nested sampling, multilevel sampling); recruitment and sampling (procedure, site(s), participants, sample size, participant recruitment); stages of the mixed data analysis process: data reduction, data display, data transformation, data correlation, data consolidation, data comparison, and sample description (sample size, sample information, the sampling scheme for the quantitative/qualitative research, the sampling scheme for the mixed methods research). We first compiled a comprehensive list of all items. We extracted all items from each guideline, recommendation, and model included.

A checklist of all items in quality criteria was then prepared. Assessments in the framework devised by O'Cathain et al. (2008) were included, namely assessment of: a study's success, the mixed methods design of studies, the qualitative component of mixed methods

studies, the integration in mixed methods studies, and of the inferences drawn in completed reports of mixed methods studies. We then chose quality questions to be included on our list: "Is the use of mixed methods research justified?", "Is the design for mixing methods described? Priority? Purpose? Sequence? Stage of integration?", "Is the design clearly communicated?", "Is the design appropriate for addressing the research questions?", "Is each method described in sufficient detail?", "Is each method appropriate for addressing the research question?", "Is the approach to sampling and analysis appropriate for its purpose?", "Is the type of integration stated?", "Is the type of integration appropriate to the design?", "Is there clarity about which results have emerged from which methods?", and "Are the inferences appropriate?".

Five of Bryman's quality criteria were included on the list: quantitative and qualitative components, research questions, mixed methods design, rationale, and integration. The mixed methods evaluation rubric (Creamer, 2018) is important for our conceptional model. We also take the logic of the rubric into account; namely, it uses numbers and establishes levels of quality. Thus far, we have just encountered frameworks in our previous guidelines because the quality evaluation was dichotomous and the presence or absence of a criterion was being evaluated. In our list, we included all four of Creamer's mixed methods evaluation criteria: rationale, research questions, phases of mixing, degree of comparisons. Our conceptual model relies on all five methodological quality criteria from the MMAT model: rationale, integration, interpretation of outputs of the integration, divergencies and inconsistencies, and adherence to the quality criteria.

Guidelines for intervention studies were also included in the conceptual model. From CONSORT, we added the following items to the comprehensive list: trial design, participants, interventions, outcomes, sample size, randomization, implementation, blinding, statistical methods, participant flow, recruitment, baseline data, numbers analyzed, outcomes, and estimation. From TIDieR, items added to the list are: brief name, why (rationale, theory or goal), what (materials, procedures), who provided, how (modes of delivery), where, when and how much, tailoring, modifications, and how well. Our list also includes several items from the GB-BCIs model: intervention design, intervention content, participants, and facilitators. Quality criteria for randomized and non-randomized studies contain the items: randomization, groups (intervention, control), participants, and measurements.

6.2. Data extraction

We recorded the frequency of each item across all guidelines. Items most frequently included in the guidelines and quality criteria for mixed methods related to rationale/ justification, research question, mixed methods design, sampling, methods, and integration. Table 2 shows the number of general guidelines, specific guidelines, guidelines in associations and quality criteria for mixed methods and the number of items most often included in these guidelines and quality criteria.

Items from four guidelines for intervention studies were also added to the comprehensive list. There are not many overlapping item. We will include the following items in the conceptual model: trial design, participants, groups (intervention and control) interventions, intervention content, sample size, randomization, statistical methods, recruitment, baseline data, measurements, numbers analyzed.

Our next step was to include the extracted items on the list in the conceptual model. We made a plan for how to organize the items in groups. We revised the checklist and also added items for quantitative and qualitative methods and general information about the research.

Table 2: The number of items most frequently included in guidelines, recommendations, models, and quality criteria for mixed methods

	General guidelines, recommendations and models ($N = 13$)	Specific guidelines, recommendations and models ($N = 10$)	Guidelines in associations ($N = 4$)	Quality criteria for mixed methods ($N = 4$)
Rationale / justification	10	7	4	4
Research question	9	5	3	4
Mixed methods design	10	9	4	4
Sampling	7	7	3	4
Methods (data collection, data analysis)	9	9	4	4
Integration	11	9	4	4

7. Conceptual model for assessing mixed methods in intervention studies – quality criteria

We constructed the conceptual model and divided it into three sections: (1) topic; (2) checklist items; and (3) item description. The model contains five topics: (1) research – 11 items which describe general data about the research; (2) intervention – 12 items which describe the intervention; (3) quantitative methods – 21 items which describe quantitative methods; (4) qualitative methods – 22 items which describe qualitative methods; and (5) mixed methods – 16 items which describe mixed methods. Each item is a variable (nominal, ordinal or numeric).

Each topic consists of checklist items (Table 3). The first topic "Research" contains the following items: type of research, field of study, purpose/aim/goal of the research, number of studies, number of phases, methods, ethical approval, informed consent, rewards/incentives, research duration and flowchat of the study design. The second topic "Intervention" contains the items: type of study, intervention phase, type of intervention, type of experiment, type of RCT, intervention standards, number of groups, intervention group, size, control group, size, randomization, allocation. The third topic "Quantitative methods" contains the items: methods, instruments, number of measurements, number of pre-intervention measurements, number of between-intervention measurements, number of post-intervention measurements, time between end-of-intervention and post-intervention measurements, data collection instrument 1, data collection instrument 2, data collection instrument 3. "Qualitative methods" is the fourth topic and contains the items: methods, instruments, number of measurements, number of pre-intervention measurements, number of between-intervention measurements, number of post-intervention measurements, time between end-of-intervention and post-intervention measurements, data collection instrument 1, data collection instrument 2, data collection instrument 3. "Mixed methods" is the fifth topic in our conceptual model and contains the:

mixed methods, mixed methods design, description, rationale/justification for mixed methods, mixed methods research question, level of mixed methods, level of interaction between quantitative and qualitative strands, mixing of methods, priority, timing, integration, integration where, integration how, data transformation, and units.

Each checklist item is either a categorical, ordinal, or numerical variable. Under the item description Checklist items in the conceptual model we can find which are the categorical variables that have two, three, or more values. The checklist items which present the time of measurements are ordinal variables. Numeric variables are the number of groups, intervention groups, and control groups.

In the next research step, we plan to undertake a systematic review of articles in SpringerLink, PubMed, and Web of Science which use mixed methods methodology in intervention studies. We will apply our conceptual model as we conduct this systematic review. The conceptual model will serve as a coding scheme with quantitative and qualitative data. At the end, we will analyze these data and obtain results which will amount to a quality assessment of the use of mixed methods in intervention studies. The results of the conceptual model will be used to develop guidelines for researchers who employ mixed methods in intervention studies.

Table 3: Components of the conceptual model

Topic		Item description
Research		
1.1	Type of research	1 = protocol // 2 = research article // 3 = pilot study
1.2	Field of study	1 = health // 2 = psychology // 3 = education
1.3	Purpose/aim/goal of research	
1.4	No. of studies	1 = one intervention, one phase // 2 = one intervention, multi-stage // 3=two different studies
1.5	No. of phases	1 = one // 2 = two // 3 = three
1.6	Methods	1 = single method qual // 2 = single method quant // 3 = multi method qual // 4 = multi method quant // 5 = mixed methods
1.7	Ethical approval	1 = yes // 0 = no
1.8	Informed consent	1 = yes // 0 = no If 1=yes 1=verbal, 2=written, 3=verbal and written
1.9	Rewards, incentives	1 = yes // 0 = no
1.10	Research duration	
1.11	Flowchart of study design	1 = yes // 0 = no
Intervention		
2.1	Type of study	1 = intervention // 2 = evaluation // 3 = intervention and evaluation

continued ...

Topic		Item description
2.2	Intervention phase	1 = pilot intervention // 2 = intervention development // 3 = intervention implementation // 4 = process evaluation // 5 = intervention evaluation
2.3	Type of intervention	1 = experiment // 2 = quasi-experiment // 3 = not written
2.4	Type of experiment (if experimental design)	1 = randomized controlled trial // 2 = parallel design // 3 = multiple-baseline design // 4 = cross sectional research // 5 = prospective study // 6 = longitudinal design // 7 = retrospective study // 8 = pretest–posttest design // 9 = before and after design // 10 = observational study // 11 = stepped-wedge design
2.5	Type of RCT (if RCT)	1 = explanatory RCT // 2 = pragmatic RCT // 3 = feasibility RCT // 4 = pilot RCT // 5 = exploratory RCT // 6 = cluster RCT // 7 = N of 1 trials // 8 = factorial RCT // 9 = adaptive RCT
2.6	Intervention standards	1 = CONSORT // 2 = REAIM // 9 = NOT SPECIFIED
2.7	No. of groups	1 = 1 // 2 = 2 // 3 = 3
2.8	Intervention group	1 = 1 // 2 = 2 // 3 = 3
2.9	Size	1 = yes // 2 = no
2.10	Control group	
2.11	Size	1 = yes // 2 = no
2.12	Randomization	1 = simple randomization // 2 = block randomization // 3 = stratified block randomization // 4 = dynamic (adaptive) random allocation
2.13	Allocation	1 = random allocation // 2 = non-random allocation
Quantitative methods		
3.1	Methods	1 = primary // 2 = secondary
3.2	Instruments	1 = survey // 2 = data archives // 3 = documents
3.3	No. of measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more
3.4	No. of pre-intervention measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more
3.5	No. of between-intervention measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more
3.6	No. of post-intervention measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more

continued . . .

Topic		Item description
3.7	Time between end of intervention and post intervention measurements (in months)	1 = one week // 2 = two weeks // 3 = three weeks // 4 = one month
3.8	Data collection instrument 1	1 = survey // 2 = data archives // 3 = chart audits // 4 = analytics // 5 = other
3.9	Data collection instrument 2	1 = survey // 2 = data archives // 3 = chart audits // 4 = analytics // 5 = other
3.10	Data collection instrument 3	1 = survey // 2 = data archives // 3 = chart audits // 4 = analytics // 5 = other
Participants 1		
3.11	Recruitment strategy	1 = recruiting via personal and professional connections // 2 = recruiting via fliers // 3 = recruiting via advertisements // 4 = recruiting via emails and letters
3.12	Recruitment duration	
3.13	Sampling site	1 = school district // 2 = municipality // 3 = rural based location // 4 = city-based location // 5 = hospital // 6 = general practices // 7 = care facilities // 8 = state // 9 = other
3.14	Units of observation	1 = individuals // 2 = groups
3.15	Sampling strategy	1 = probability sampling // 2 = non-probability sampling
3.16	Inclusion criteria	1 = yes // 0 = no
3.17	Exclusion criteria	1 = yes // 0 = no
3.18	Data collection instruments	1 = survey // 2 = data archives // 3 = chart audits // 4 = analytics // 5 = other
3.19	Data analysis method	1 = descriptive statistics // 2 = inferential statistics
3.20	Data analysis software	1 = SPSS // 2 = R // 3 = STATA // 4 = other
3.21	Statistical power calculations (3.2	1 = yes // 2 = no
Participants 2		
3.22	Recruitment strategy	1 = recruiting via personal and professional connections // 2 = recruiting via fliers // 3 = recruiting via advertisements // 4 = recruiting via emails and letters
3.23	Recruitment duration	
3.24	Sampling site	1 = school district // 2 = municipality // 3 = rural-based location // 4 = city-based location // 5 = hospital // 6 = general practices // 7 = care facilities // 8 = state // 9 = other

continued . . .

Topic		Item description
3.25	Units of observation	1 = individuals // 2 = groups
3.26	Sampling strategy	1 = probability sampling // 2 = non-probability sampling
3.27	Inclusion criteria	1 = yes // 0 = no
3.28	Exclusion criteria	1 = yes // 0 = no
3.29	Data collection instruments	1 = survey // 2 = data archives // 3 = chart audits // 4 = analytics // 5 = other
3.30	Data analysis method	1 = descriptive statistics // 2 = inferential statistics
3.31	Data analysis software	1 = SPSS // 2 = R // 3 = STATA // 4 = other
3.32	Statistical power calculations	1 = yes // 2 = no
Participants 3		
3.33	Recruitment strategy	1 = recruiting via personal and professional connections // 2 = recruiting via fliers // 3 = recruiting via advertisements // 4 = recruiting via emails and letters
3.34	Recruitment duration	
3.35	Sampling site	1 = school district // 2 = municipality // 3 = rural-based location // 4 = city-based location // 5 = hospital // 6 = general practices // 7 = care facilities // 8 = state // 9 = other
3.36	Units of observation	1 = individuals // 2 = groups
3.37	Sampling strategy	1 = probability sampling // 2 = non-probability sampling
3.38	Inclusion criteria	1 = yes // 0 = no
3.39	Exclusion criteria	1 = yes // 0 = no
3.40	Data collection instruments	1 = survey // 2 = data archives // 3 = chart audits // 4 = analytics // 5 = other
3.41	Data analysis method	1 = descriptive statistics // 2 = inferential statistics
3.42	Data analysis software	1 = SPSS // 2 = R // 3 = STATA // 4 = other
3.43	Statistical power calculations	1=yes 2=no
Qualitative methods		
4.1	Methods	1 = primary // 2 = secondary
4.2	Instruments	1 = interview // 2 = focus group // 3 = observation // 4 = case study // 5 = field notes // 6 = workshop
4.3	No. of measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more

continued . . .

Topic		Item description
4.4	No. of pre-intervention measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more
4.5	No. of between- intervention measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more
4.6	No. of post- intervention measurements	1 = 1 // 2 = 2 // 3 = 3 // 4 = 4 // 5 = 5 // 6 = 6 or more
4.7	Time between end of intervention and post intervention measurements (in months)	1 = one week // 2 = two weeks // 3 = three weeks // 4 = one month
4.8	Data collection instrument 1	1 = interview // 2 = focus groups // 3 = observation // 4 = other
4.9	Data collection instrument 2	1 = interview // 2 = focus groups // 3 = observation // 4 = other
4.10	Data collection instrument 3	1 = interview // 2 = focus groups // 3 = observation // 4 = other
Participants 1		
4.11	Recruitment strategy	1 = recruiting via personal and professional connections // 2 = recruiting via fliers // 3 = recruiting via advertisements // 4 = recruiting via emails and letters
4.12	Recruitment duration	
4.13	Sampling site	1 = school district // 2 = municipality // 3 = rural-based location // 4 = city-based location // 5 = hospital 6 = general practices // 7 = care facilities // 8 = state // 9 = other
4.14	Units of observation	1 = individuals // 2 = groups
4.15	Sampling strategy	1 = purposeful sampling // 2 = convenience sampling
4.16	Inclusion criteria	1 = yes // 0 = no
4.17	Exclusion criteria	1 = yes // 0 = no
4.18	Data collection instruments	1 = interview // 2 = focus groups // 3 = observation // 4 = other
4.19	Data analysis method	1 = content analysis // 2 = narrative analysis // 3 = discourse analysis // 4 = grounded theory
4.20	Data analysis software	1 = Atlas.ti // 2 = Nvivo // 3 = MAXQDA // 4 = other
4.21	No. of raters	1 = 1 // 2 = 2 // 3 = 3 or more
4.22	Interrater agreement	1 = yes // 2 = no

continued . . .

Topic		Item description
Participants 2		
4.23	Recruitment strategy	1 = recruiting via personal and professional connections // 2 = recruiting via fliers // 3 = recruiting via advertisements // 4 = recruiting via emails and letters
4.24	Recruitment duration	
4.25	Sampling site	1 = school district // 2 = municipality // 3 = rural-based location // 4 = city-based location // 5 = hospital // 6 = general practices // 7 = care facilities // 8= state // 9 = other
4.26	Units of observation	1 = individuals // 2 = groups
4.27	Sampling strategy	1 = purposeful sampling // 2 = convenience sampling
4.28	Inclusion criteria	1 = yes // 0 = no
4.29	Exclusion criteria	1 = yes // 0 = no
4.30	Data collection instruments	1 = interview // 2 = focus groups // 3 = observation // 4 = other
4.31	Data analysis method	1 = content analysis // 2 = narrative analysis // 3 = discourse analysis // 4 = grounded theory
4.32	Data analysis software	1 = Atlas.ti // 2 = Nvivo // 3 = MAXQDA // 4 = other
4.33	No. of raters	1 = 1 // 2 = 2 // 3 = 3 or more
4.34	Interrater agreement	1 = yes // 2 = no
Participants 3		
4.35	Recruitment strategy	1 = recruiting via personal and professional connections // 2 = recruiting via fliers // 3 = recruiting via advertisements // 4 = recruiting via emails and letters
4.36	Recruitment duration	
4.37	Sampling site	1 = school district // 2 = municipality // 3 = rural-based location // 4 = city-based location // 5 = hospital // 6 = general practices // 7 = care facilities // 8 = state // 9 = other
4.38	Units of observation	1 = individuals // 2 = groups
4.39	Sampling strategy	1 = purposeful sampling // 2 = convenience sampling
4.40	Inclusion criteria	1 = yes // 0 = no
4.41	Exclusion criteria	1 = yes // 0 = no
4.42	Data collection instruments	1 = interview // 2 = focus groups // 3 = observation // 4 = other
4.43	Data analysis method	1 = content analysis // 2 = narrative analysis // 3 = discourse analysis // 4 = grounded theory
4.44	Data analysis software	1 = Atlas.ti // 2 = Nvivo // 3 = MAXQDA // 4 = other
4.45	No. of raters	1 = 1 // 2 = 2 // 3 = 3 or more

continued . . .

Topic		Item description
4.46	Interrater agreement	1 = yes // 2 = no
Mixed methods		
5.1	Mixed methods	1 = true mixed methods // 2 = quasi mixed methods // 3 = partially mixed methods
5.2	Mixed methods design	
5.3	Description	If 1 = yes name: If 0=no descriptive
5.4	Rationale/justification for mixed methods	1 = yes // 0 = no
5.5	Mixed methods research question	1 = yes // 0 = no
5.6	Mixed methods	1 = ON THE LEVEL OF UNITS (within phases, on same participants qual and quant) // 2 = ON THE LEVEL OF DESIGN (between phases, one phase is qual, one phase is qual) // 3 = both
5.7	Level of interaction between quan and qual	1 = independent // 2 = interactive
5.8	Mixing of methods	1 = on the level of design // 2 = on the level of units // 3 = both
5.9	Priority	1 = quan // 2 = qual // 3 = equal
5.10	Timing	1 = concurrent // 2 = sequential
5.11	Integration	1 = yes // 0 = no
5.12	Integration where	1 = data collection // 2 = analysis // 3 = interpretation // 4 = combination
5.13	Integration how	1 = merge // 2 = link // 3 = transform // 4 = other
5.14	Data transformation	1 = yes // 2 = no If 1=yes 1=qual v quant 2=quanti v qual 3=both 4=none 5=not reported 6=not applicable
5.15	Units	1 = identical units // 2 = identical groups // 3 = partially identical // 4 = different
5.16	Units	1 = the same level of units // 2 = different level of units

8. Conclusion

This paper describes three guidelines available to the researcher while using mixed methods research in intervention studies: basic procedures in implementing a mixed methods experimental design (Creswell and Plano Clark, 2018), practical guidance for using qualitative research with an RCT (O'Cathain, 2018), and a mixed methods appraisal tool for appraising the methodological quality of randomized controlled trials, non-randomized studies, and mixed methods – MMAT (Hong et al., 2018). While on one hand these guidelines are too general since they do not take different experimental and quasi-experimental designs into

account, on the other hand they are too specific because they describe in too much detail a certain experimental design – a randomized controlled trial. They also lack the relationship between mixed methods research and intervention studies.

These three shortcomings explain the reason for developing a conceptual model for mixed methods in intervention studies so as to overcome the deficiencies of the existing guidelines. This paper describes the development of a conceptual model based on the current guidelines, recommendations, models, and quality criteria for mixed methods, guidelines for intervention studies, and the existing limited guidelines for mixed methods in intervention studies. The new conceptual model improves on the existing guidelines by containing all experimental and quasi-experimental designs along with the relationship between mixed methods research and intervention studies. In the next step, we shall assess the quality of mixed methods research in intervention studies.

We made an overview of guidelines, recommendations, models, and quality criteria for mixed methods research and guidelines for intervention research. A checklist of all items in these guidelines was then prepared. We recorded the frequency of each item across all guidelines and extracted the items most frequently included in the guidelines and quality criteria. In the next step, the extracted list items were included in a conceptual model. We also included items for quantitative and qualitative methods and general information about the research.

The conceptual model is the outcome of the overview and evaluation of guidelines, recommendations, models, and quality criteria for mixed methods and intervention studies. It is divided into three sections and contain five topics: (1) research – 11 items describing general data about the research; (2) intervention – 12 items describing the intervention; (3) quantitative methods – 21 items describing the quantitative methods; (4) qualitative methods – 22 items describing the qualitative methods; and (5) mixed methods – 16 items describing the mixed methods. Each item is a variable (nominal, ordinal or numeric).

Our conceptual model extends previous models in four respects, namely, it can be used: (1) for all types of experimental and quasi-experimental designs; (2) for complex interventions with many participants, sampling sites, and components; (3) in all types of disciplines (health science, psychology, education, etc.); and (4) in all phases of intervention (development, feasibility, implementation or process evaluation).

Another important contribution of our conceptual model is the assessment of mixed methods research in intervention studies. We plan to make a systematic review of interventions using mixed methods research in three databases: SpringerLink, PubMed, and Web of Science. Results of this assessment will help create guidelines for mixed methods research in intervention studies.

The study has several limitations. We constructed the conceptual model on the basis of relevant literature. It is possible that some guidelines for mixed methods in certain disciplines were not included because mixed methods methodology use is increasingly popular. Second, guidelines for mixed methods may be published in the journals of associations that we did not review. Another limitation is that the literature review only considered sources in English and it is possible that guidelines have also been developed in other languages. A review of guidelines for mixed methods in other languages and for other associations and disciplines is essential to confirm that all important elements of the guidelines, recommendations, and models are included in our conceptual model.

The outcome of the evaluation of the existing guidelines and model was the construction of a conceptual model. This model will be utilized to assess the quality of mixed methods research in intervention studies to increase the methodological quality of mixed methods

methodology in future intervention research.

References

[1] Albright K., Gechter K., and Kempe A. (2013): Importance of mixed methods in pragmatic trials and dissemination and implementation research. *Academic Pediatric*, **13**(5), 400–407.

[2] Bamberger, M. (2012): Introduction to mixed methods in impact evaluation. Impact Evaluation Notes, 3. The Rockefeller Foundation. `http://www.interaction.org/impact-evaluation-notes`

[3] Boeije, H.R., Drabble, S.J., and O'Cathain, A. (2015): Methodological challenges of mixed methods intervention evaluations. *Methodology*, **11**(4), 119–125.

[4] Borek, A.J., Abraham, C., Smith, J.R., Greaves, C.J., and Tarrant, M. (2015): A checklist to improve reporting of group-based behaviour-change interventions. *BMC Public Health*, **15**(1), 963.

[5] Bradt, J., Burns, D.S., and Creswell, J.W. (2013): Mixed methods research in music therapy research. *Journal of Music Therapy*, **50**(2), 123–148.

[6] Brown, K.M., Elliott, S.J., Leatherdale, S.T., and Robertson-Wilson, J. (2015): Searching for rigour in the reporting of mixed methods population health research: A methodological review. *Health Education Research*, **30**(6), 811–839.

[7] Bryman, A. (2014): June 1989 and beyond: Julia Brannen's contribution to mixed methods research. *International Journal of Social Research Methodology*, **17**(2), 121–131.

[8] Collins, K.M., Onwuegbuzie, A.J., and Sutton, I.L. (2006): A model incorporating the rationale and purpose for conducting mixed-methods research in special education and beyond. *Learning Disabilities: A Contemporary Journal*, **4**(1), 67–100.

[9] Creamer, E.G. (2018): *An introduction to fully integrated mixed methods research*. Thousand Oaks, CA: Sage.

[10] Creswell, J. and Plano Clark, V. (2007): *Designing and conducting mixed methods research*. Thousand Oaks, CA: Sage.

[11] Creswell, J. and Plano Clark, V. (2011): *Designing and conducting mixed methods research*. Thousand Oaks, CA: Sage.

[12] Creswell, J.W. (2015): *A concise introduction to mixed methods research*. Thousand Oaks, CA: Sage.

[13] Creswell, J.W. and Plano Clark, V.L. (2018): *Designing and conducting mixed methods research*. Thousand Oaks, CA: Sage.

[14] Creswell, J.W., Fetters, M.D., and Ivankova, N.V. (2004): Designing a mixed methods study in primary care. *The Annals of Family Medicine*, **2**(1), 7–12.

[15] Doyle, L., Brady, A.M., and Byrne, G. (2016): An overview of mixed methods research. *Journal of Research*, **14**(2), 175–185.

[16] Drabble, S.J. and O'Cathain, A. (2015): Moving from randomized controlled trials to mixed methods intervention evaluations. In S. Hesse-Biber and R.B. Johnson (Eds): *The Oxford Handbook of Multimethod and Mixed Methods Research*, 406–425. New York, NY: Oxford University Press.

[17] Fabregues and Molina-Azorin (2017): Addressing quality in mixed methods research: A review and recommendations for future agenda. *Quality & Quality*, **51**(6), 2847–2863.

[18] Farquhar, M.C., Ewing, G., and Booth, S. (2011): Using mixed methods to develop and evaluate complex interventions in palliative care research. *Palliative Medicine*, **25**(8), 748–757.

[19] Farquhar, M., Preston, N., Evans, C.J., Grande, G., Short, V., Benalia, H., Higginson, I.J., and Todd, C. (2013): Mixed methods research in the development and evaluation of complex interventions in palliative and end-of-life care: Report on the MORECare Consensus Exercise. *Journal of Palliative Medicine*, **16**(12), 1550–1560.

[20] Fetters, M.D. and Freshwater, D. (2015): Publishing a methodological mixed methods research article. *Journal of Mixed Methods Research*, **9**(3), 203–213.

[21] Gallo, J.J and Lee, S.Y. (2016): Mixed methods in behavioral intervention research. In L.N. Gitlin and S.J. Czaja (Eds.): *Behavioral intervention research – designing, evaluating and implementing*, 195–212. New York, NY: Springer.

[22] Glover-Kudon, R. (2010): Guidelines for conducting a high-quality mixed-methods dissertation. American Evaluation Association Annual Conference. `https://eval.connectedcommunity.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=39606eed-cb0c-4dd3-8807-27533ce85300`

[23] Graff, J.C. (2017): Mixed methods research. In Hall, H.R. and L.A. Roussel (Eds.): *Evidence-based practice: An integrative approach to research, administration, and practice*, 47–66. Burlington, MA: Jones & Barlett.

[24] Greene, J. (2008): Is mixed methods social inquiry a distinctive methodology? *Journal of Mixed Methods Research*, **2**(1), 7–22.

[25] Grissmer, D.W. (2016): *A guide to incorporating multiple methods in randomized contolled trials to assess intervention effects*. Washington, DC: American Psycolocigal Association.

[26] Guest, G. (2012): Describing mixed methods research. *Journal of Mixed Methods Research*, **7**(2), 141–151.

[27] Guest, G. and Fleming, P.J. (2014): Mixed methods research. In G. Guest and E. Namely (Eds.): *Public Health Research Methods*, 581–610. Los Angeles, CA: Sage.

[28] Hesse-Biber, S. (2012): Weaving a multimethodology and mixed methods praxis into randomised controlled trials to enhance credibility. *Qualitative Inquiry*, **18**(10), 876–889.

[29] Hoffmann, T.C., Glasziou P.P., Ruairidh, M., Moder, D., Barbour, V., Johnston, M., Lamb, S., Dixon-Woods, M., and Wyatt, J.C. (2014): Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *British Medical Journal*, **7**(348), g1687.

[30] Hong, Q.N., Gonzales-Reyes, A., and Pluye, P. (2018): Improving the usefulness of a tool for appraising the quality of qualitative, quantitative and mixed methods studies, the Mixed Methods Appraisal Tool (MMAT). *Journal of Evaluation in Clinical Practice*, **24**(3), 459–467.

[31] Ivankova, N.V. (2014): *Mixed methods applications in action research. From methods to community action*. Thousand Oaks, CA: Sage.

[32] Jalongo, M.R. and Saracho, O.N. (2016): *Writing for publications: Transitions and tools that support scholars' success*. Switzerland: Springer.

[33] Jimenez, E., Waddington, H., Goel, N., Prost, A., Pullin, A., White, H., Lahiri. S., and Narain, A. (2018): Mixing and matching: using qualitative methods to improve quantitative impact evaluations (Ies) and systematic reviews (Srs) of development outcomes. *Journal of Development Effectiveness*, **10**(4), 400–421.

[34] Leech, N.L. (2012): Writing mixed research reports. *American Behavioral Scientist*, **56**(6), 866–881.

[35] Leech, N.L. and Onwuegbuzie, A.J. (2010): Journal article reporting standards for qualitative primary, qualitative meta-analytic, and mixed methods research in psychology: The APA Publications and Communications Board task force report. *American Psychologist*, **73**(1): 26–46.

[36] Lewin, S., Glenton, C., and Oxman, A.D. (2009): Use of qualitative methods alongside randomised controlled trials of complex healthcare interventions: Methodological study. *British Medical Journal*, **339**, b3496.

[37] Levitt, H.M., Bamberg, M., Creswell, J.W., Frost, D.M., Josselson, R., and Suarez-Orozco, C. (2018): Journal article reporting standards for qualitative primary, qualitative meta-analytic, and mixed methods research in psychology: The APA Publications and Communications Boart task force report. *American Psychologist*, **73**(1), 26–46.

[38] Maxwell, J.A. and Loomis, D. (2003): Mixed methods design: An alternative approach. In A. Tashakkori and C. Teddlie (Eds.): *Handbook of mixed methods in social and behavioral research*, 241–271. Thousand Oaks, CA: Sage.

[39] Maxwell, J.A. (2012): *A realist approach for qualitative research*. Thousand Oaks, CA: Sage.

[40] NIH Office of Behavioral and Social Sciences (2018): *Best practices for mixed methods research in the health sciences*. Bethesda, MA: National Institutes of Health.

[41] Noyes, J., Booth A., Moore, G., Flemming K., Tuncalp, O., and Shakibazadeh, E. (2019): Synthesising quantitative and qualitative evidence to inform guidelines on complex interventions: Clarifying the purposes, designs and outlinining some methods. *British Medical Journal Global Health*, **4**, e000893.

[42] O'Cathain, A., Murphy, E., and Nicholl, J. (2008): The quality of mixed methods studies in health services research. *Journal of Health Services Research & Policy*, **13**(2), 92–98.

[43] O'Cathain, A., Murphy, E., and Nicholl, J. (2010): Three techniques for integrating for integrating data in mixed methods studies. *British Medical Journal*, **341**, 1147–1150.

[44] O'Cathain, A., Thomas, K.J., Drabble, S.J., Rudolph, A., and Hewison, J. (2013): What can qualitative research do for randomised controlled trials? A systematic mapping review. *British Medical Journal*, **3**, e002889.

[45] O'Cathain, A. (2018): *A practical guide to using qualitative research with randomized controlled trials*. New York, NY: Oxford University Press.

[46] Onwuegbuzie, A. J. and Teddlie, C. (2003): A framework for analyzing data in mixed methods research. In A. Tashakkori and C. Teddlie (Eds.): *Handbook of mixed methods in social and behavioral research*, 351–383. Thousand Oaks, CA: Sage.

[47] Onwuegbuzie, A.J. and Collins, K.M. (2007): A typology of mixed methods sampling designs in social science research. *Qualitative Report*, **12**(2), 281–316.

[48] Onwuegbuzzie, A.J. and Corrigan, J.A. (2014): Improving the quality of mixed research reports in the field of human resource development and beyond: A call for rigor as an ethical practice. *Human Resource Development Quarterly*, **25**(3), 273–299.

[49] Palinkas et al. (2019): Innovations in mixed methods evaluations. *Annual Review of Public Health*, **40**(1), 423–442.

[50] Protheroe, J., Bower, P., and Chew-Graham, C. (2008): The use of mixed methodology in evaluating complex interventions: Identifying patient factors that moderate the effects of a decision aid. *Family Practice*, **24**(6), 594–600.

[51] Sandelowski, M. (1996): Using qualitative methods in intervention studies. *Research in Nursing and Health*, **19**(4), 359–364.

[52] Schifferdecker, K.E. and Reed V.A. (2009): Using mixed methods research in medical education: Basic guidelines for researchers. *Medical Education*, **43**(7), 637–644.

[53] Schulz, K.F., Altman, D.G., and Moher, D. (2010): CONSORT 2010 Statement: Updated guidelines for reporting parallel group randomised trials. *Journal of Clinical Epidemiology*, **63**(8), 834–840.

[54] Song, M., Happ, M.B., and Sandelowski, M. (2010): Development of a tool to assess fidelity to a psycho-educational intervention. *Journal of Advanced Nursing*, **66**(3), 673–682.

[55] Schoonenboom, J. and Burke Johnson, R. (2017): How to construct a mixed methods design. *Kölner Zeitschrift für Soziologie and Sozialpsychologie*, **69**(7), 107–131.

[56] Tashakkori, A. and Teddlie, C. (1998): *Mixed methodology: Combining qualitative and quantitative approaches*. Thousand Oaks, CA: Sage.

[57] Tashakkori, A. and Teddlie, C. (2003): *Handbook of mixed methods in social & behavioral research*. Thousand Oaks, CA: Sage.

[58] Tashakkori, A. and Teddlie, C. (2009): *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioral sciences*. Thousand Oaks, CA: Sage.

[59] Tashakkori, A. and Teddlie, C. (2010): *Handbook of mixed methods in social and behavioral research*. Thousand Oaks, CA: Sage.

[60] Venkatesh, V., Brown, S.A., and Bala, H. (2013): Bridging the qualitative – quantitative divide: Guidelines for conducting mixed methods research in information systems. *MIS Quarterly*, **36**(1), 21–54.

[61] Venkatesh, V., Brown, S. A., and Sullivan, Y.W. (2016): Guidelines for conducting mixed-methods research: An extension and illustration. *Journal of the Association for Information Systems*, **17**(7), 435–495.

[62] Wisdom, J.P., Cavaleri, M.A., Onwuegbuzie, A.J., and Green, C.A. (2012): Methodological reporting in qualitative, quantitative, and mixed methods health services research articles. *Health Services Research*, **47**(2), 721–745.

[63] Woolcock, M. (2018): Reasons for using mixed methods in the evaluation of complex projects. In: M. Nagatsu and A. Ruzzene (Eds): *Philosophy and interdisciplinary social science: A dialogue*, 149–171. London: Bloomsbury Academic.