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DOI:
10.1016/j.eujim.2018.10.017

Document Version
Accepted author manuscript

Accepted Manuscript

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PII: S1876-3820(18)30295-6
DOI: https://doi.org/10.1016/j.eujim.2018.10.017
Reference: EUJIM 860

To appear in:

Received date: 4 June 2018
Revised date: 28 September 2018
Accepted date: 27 October 2018

Please cite this article as: Donald G, A Brief Summary of Pilot and Feasibility Studies: Exploring Terminology, Aims, and Methods, *European Journal of Integrative Medicine* (2018), https://doi.org/10.1016/j.eujim.2018.10.017

A Brief Summary of Pilot and Feasibility Studies: Exploring Terminology, Aims, and Methods

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Abstract

Introduction:

There is limited guidance on methods for pilot and feasibility studies and, as a result, they are often poorly done or poorly reported.

All CAM/IM modalities can be considered to be complex interventions; as such, the research on this topic faces additional challenges when compared to pharmaceutical studies. Pilot and feasibility studies should take account of intervention complexity, implementation, and acceptability; this focus suits the wider needs of CAM research and potentially contributes to improved study quality.

This opinion paper provides a narrative summary of the literature relating to terminology & conceptual clarity, aims & objectives, epistemology, and research methods.

Terminology & Conceptual Clarity:

Definitions and conceptualisations of pilot and feasibility studies vary; attempts are made here to identify commonality.

Recommended Aims & Objectives for Pilot & Feasibility Studies:

The main purpose of pilot and feasibility studies is to assess the feasibility, acceptability, and potential effectiveness of new interventions or interventions in new contexts. Where a pilot trial is conducted, the feasibility of trial processes should also be evaluated.

Epistemology, Methods & Research Frameworks:

Mixed methods is the most valuable data collection strategy for pilot and feasibility studies and their use can be successfully underpinned by a pragmatic epistemological stance. Several frameworks relevant to pilot and feasibility testing are explored.

Conclusion:

Rigorous feasibility testing is necessary to underpin high quality CAM/IM research. Employing mixed methods within an appropriate framework will generate vital data for optimising CAM/IM research and intervention delivery.

1. Introduction

Pilot and feasibility studies are often poorly done or poorly reported. Thabane et al (2010) noted that the availability of guidance or textbooks on feasibility methods is limited. This paper explores selected literature relevant to issues of terminology & conceptual clarity and aims & objectives, before moving on to consider an appropriate epistemology and preferable methods & research frameworks.

All Complementary & Alternative Medicine (CAM) and Integrative Medicine (IM) modalities can be considered to be complex interventions (MRC 2008), consisting of several interacting components that are often considered to work synergistically. Research of any intervention that meets this definition faces the additional challenges that pharmaceutical studies – based on 'pill', 'no pill', or 'fake pill' – do not. Consequently, it is vital that intervention complexity is considered in CAM/IM research, especially during the feasibility/piloting stage, where crucial refinements to study design and intervention can be made.

Pilot and feasibility studies are a necessary step in the research process and the results can inform key concerns including intervention delivery, contextual factors, and implementation (MRC 2014). Given the competing priorities in balancing the individuality of CAM interventions with the standardisation of empirical research methods, the results of early-stage, developmental research are instrumental for improving subsequent study design and optimising intervention delivery. This is important for adapting CAM/IM methodologies to the distinct needs of different groups of people. In their synthesis of 170 papers on CAM methodology, Fischer et al (2012) included recommendations for addressing both the complexity of CAM and the methodological issues that are the focus of pilot and feasibility studies. Engaging in rigorous feasibility assessment during the early stages of CAM/IM research should ultimately yield studies of excellent methodological quality. The number of CAM/IM pilot and feasibility studies has been growing; however, often the rigour and scope of these studies is sub-optimal (Donald 2016).

The aim of this opinion piece is to provide a brief narrative review of the key literature relating to conceptual clarity, aims, epistemology, and methods, in order to contribute a simple proposition to the field that distinguishes between pilots and feasibility studies.

2. Terminology & Conceptual Clarity

Firstly, it is important to establish what is meant by the terms *pilot study* and *feasibility study*, as both are used throughout the literature. Some suggest they are synonymous (Van Teijlingen & Hundley 2001, Lancaster et al 2004, Arnold et al 2009, Thabane et al 2010) whilst others suggest that they are distinct approaches (Arain et al 2010, Shanyinde et al 2011, Bugge et al 2013).

The *Developing and Evaluating Complex Interventions* (MRC 2008) guidelines use both terms but do not seem to distinguish between them. However, they do propose that objectives should include exploration of factors like intervention acceptability, compliance, intervention delivery, recruitment, and retention. Van Teijlingen & Hundley (2001) use the terms synonymously, describing a pilot study as either the testing of a new research instrument or a feasibility study that is a small scale trial, in preparation of a major study. Lancaster et al (2004), whilst primarily using the term *pilot study*, used both 'pilot' and 'feasibility' as keywords in the literature search underpinning their paper recommending good practice in this type of development work. The interchangeable use of these terms with no clear distinction has been identified by Arnold et al (2009), although they caution against the use of the term *feasibility study* as they argue it does not encompass the scope of pilot studies. While exploring the different definitions of these studies available on the internet, Thabane et al (2010) concluded that a pilot study is the same as a feasibility study, in that is intended to inform the planning of a larger, subsequent study. They do, however, propose that assessment of feasibility is an important objective in a pilot study.

In contrast, others have posited that pilot and feasibility studies are indeed distinct approaches to early-stage research (Arain et al 2010, Shanyinde et al 2011, Bugge et al 2013). Pilot studies have been posited as miniature versions of a full RCT, undertaken to test whether all of the components of the research design will work together, whilst feasibility studies have been proposed to be pieces of preliminary research, conducted to estimate the parameters needed to design a subsequent full-scale study successfully. Arain et al (2010) pointed out that feasibility studies for RCTs do not necessarily need to be randomised as long as they answer the research questions asked, which should relate to issues of feasibility and acceptability of the intervention under study and study protocols. It would appear that the acknowledgement of pilot and feasibility studies as distinct approaches has arisen in more recent publications, potentially indicating a chronological refinement in conceptual clarity.

Considering the varied definitions, this opinion paper proposes one common principle:

- All pilot studies are feasibility studies but not all feasibility studies are pilot studies.

This reflects the more comprehensive scope of pilot work when compared to feasibility studies. The key distinctions are:

- Pilots are considered to be mini-trials and so they assess feasibility and acceptability, in addition to exploring the implementation of trial processes
- Feasibility studies for a full RCT may or may not include randomisation and control groups; pilots include all the methodological elements anticipated to be employed in a fully powered trial
- Pilot studies are a very specific subset of feasibility studies, addressing the objectives covered in feasibility studies but, additionally, evaluating how well the trial processes are implemented

As a corollary, perhaps the adoption of the specific terms *pilot trial* and *feasibility study* would help to emphasise the distinction between the methods used for each.

These conclusions are supported by a Delphi study conducted by Eldridge et al (2016a), where consensus among delegates at a trial methodology conference led to recognise that pilot studies exist within the sphere of feasibility studies and that terms are not mutually exclusive. The authors conclude by advocating for the deliberate use of each term appropriately, a proposition mirrored in this paper.

3. Recommended Aims & Objectives for Pilot and Feasibility Studies

Despite inconsistent use of the terms *pilot study* and *feasibility study*, most researchers generally concur on the aims and objectives that such developmental work should address.

The complex intervention framework (MRC 2008) emphasised that feasibility studies should focus on objectives that are developmental in nature, rather than assuming an inappropriate focus on outcomes. Examples of objectives considered vital in the assessment of feasibility include:

- Evaluating recruitment potential (van Teijlingen & Hundley 2001, Lancaster et al 2004, MRC 2008, Thabane et al 2010, Arain et al 2010, Shanyinde et al 2011). Recruitment in clinical research is a notorious problem (Treweek et al 2010).
- Assessing the viability of the study protocols [including randomisation and data collection strategies] (Lancaster et al 2004, MRC 2008, Arnold et al 2009, Arain et al 2010, Shanyinde et al 2011)

- Exploring intervention acceptability, fidelity, and participant adherence (Lancaster et al 2004, MRC 2008, Bowen et al 2009, Shanyinde et al 2011)
- Acquiring the data necessary for subsequent sample size calculation (van Teijlingen & Hundley 2001, MRC 2008, Arnold et al 2009, Thabane et al 2010). Some suggest that n=30 can be sufficient for a power calculation (Browne 1995, Lancaster et al 2004)

The inappropriate focus on reporting outcome measures and hypothesis testing in studies calling themselves pilots or feasibility studies has been widespread. Arain et al (2010) found, in their review of pilot work published in 5 journals in 2007-8 (n=26), that 81% reported hypothesis testing through inferential statistics whilst only a minority reported methodological concerns that would be useful in the development of future trials, such as sample size calculation (35%) or blinding (19%). Furthermore, when randomly selecting 50 papers describing pilot and feasibility trials published in MEDLINE and EMBASE (2000-9), Shanyinde et al (2011) found that efficacy appeared to be the primary focus in 52% of papers whilst methodological concerns were only addressed in depth by 56% of papers.

It has been identified that some researchers classify their work as piloting for spurious reasons, including a lack of resources to run a larger study, that their proposal is similar in size to other studies that has been published, or that the study is being carried out by a student (Thabane et al 2010). Halpern et al (2002) argued that knowingly conducting an underpowered clinical trial and calling it a pilot is deliberate obfuscation, and may constitute unethical research conduct.

4. Epistemology, Methods, and Research Frameworks

4.1. Pragmatism & Mixed Methods

Pragmatism is a school of philosophical thought founded by American psychologists Charles Peirce (1839-1914), William James (1842-1910) and John Dewey (1859-1952). Its central tenet is that an idea is valuable if it works, is fit for its intended purpose and is capable of producing tangible consequences for the individual or for society (Rorty 1998, Gray 2013). Cornish & Gillespie (2009) argued that: pragmatism is pluralist, in that it accepts a range of forms of knowledge; it is non-relativist, in that a successful outcome is the benchmark for evaluating knowledge against; and that it is action-orientated, in that the everyday problems that people experience are considered to be the primary reality. The latter of these propositions gives a clear indication of the potential

usefulness in adopting a pragmatic position within the context of healthcare research that is focused upon improving the lives of people living with medical conditions.

Mixed method research has been posited as the third major research paradigm, next to the singular use of quantitative or qualitative methodologies (Johnson & Onwuegbuzie 2004). It has become increasingly utilised in health and social care research (Oakley et al 2006, Greene 2008, Dures et al 2010, Ostlund et al 2011) and there is potential value in mixing methods to provide optimal answers to research questions posed, particularly those that underpin pilot and feasibility studies.

A pragmatic stance has been identified as a fitting epistemological position for mixed methods research (Johnson & Onwuegbuzie 2004, Dures et al 2010) as it is not tied to a particular ontology, rather it offers an outcome-orientated method of inquiry. Paley & Lilford (2011) embraced the development of mixed methods research, identifying it as an indication of detachment from paradigmatic thinking, and propose that quantitative and qualitative methods are simply research tools, appropriate in a variety of settings.

4.2. Developing and Evaluating Complex Interventions

The MRC (2008) proposed an iterative, rather than linear, model for developing, piloting, and evaluating complex interventions. Most importantly, the development and piloting stages should be revisited when necessary before continuing to a fully powered trial. This will help maximise the chances of a successful full-scale study, representing a more efficient use of scarce research funding.

Epistemologically, the complex intervention framework (MRC 2008) is clearly based on a pragmatic philosophy. Corroborating this assertion, the language used throughout the guidance indicates its theoretical position; e.g:

> *"'Best available' methods, even if they are not theoretically optimum, may yield useful results"* (MRC 2008; p8)

Figure 1 summarises the key stages of developing and evaluating complex interventions. With respect to CAM/IM research, it will often be the case that the initial development phase can be overlooked – there is an extensive list of existing CAM/IM modalities, which means that researchers will not usually need to develop a new intervention from scratch. It may be possible, however, that some elements of the intervention can be adapted where necessary, following the findings of the feasibility assessment. It is unlikely that this will extend to the fundamental nature of the CAM/IM

intervention but should include items such as number and frequency of sessions, venue appropriateness, and characteristics of the person/people delivering the intervention.

<Insert figure 1>

It is worth noting that the MRC and National Institute for Health Research have jointly commissioned an update to the framework and this new guidance is scheduled for release in 2019 (MRC 2018).

4.3. Process Evaluation of Complex Interventions

The complex intervention framework (MRC 2008) recommended the inclusion of process evaluation in assessing the feasibility of complex interventions, defining it as a framework that *"can be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes"*, but did not specify details on how this might be operationalised. Subsequently, *Process Evaluation of Complex Interventions* (MRC 2014) was released; it is intended to cover a wide range of interventions at the individual, community and population level and is suited to help underpin the analysis of CAM/IM feasibility studies.

The three core concepts structuring process evaluations are implementation, causal mechanisms, and context.

4.3.1. Implementation

The process evaluation framework (MRC 2014) suggests that feasibility testing should include an evaluation of what was delivered and how it was delivered, so as to avoid future trials being limited by such confounders. The core concerns relating to implementation have been proposed to cover intervention fidelity (quality of the intervention), intervention dose (the quantity of what is delivered) and the reach (the extent to which the target population are exposed to the intervention).

Itemised descriptions of the intervention delivered should be provided. This should include, for example, structure and content of the intervention, details of facilitator training & experience, venue, and course format.

Intervention dose can be assessed by monitoring levels of attendance and recording levels of attrition, which may also inform intervention acceptability. In CAM/IM research, this should include details like number and duration of sessions, with any additional home practice. The possible reasons for poor adherence should also be explored.

4.3.2. Causal Mechanisms

As part of developing and piloting complex interventions, the proposed casual mechanisms should be explored and modelled (MRC 2008, 2014). The inclusion of a logic model is recommended; Figure 2 is included simply to provide an example to offer suggestions to those developing their own model (Donald 2016).

<Insert figure 2>

4.3.3. Context

Process evaluation also considers the contextual factors that may play a part in determining the effects of the intervention being researched. The framework (MRC 2014) recognises that some interventions may be better suited to certain settings or populations, more than others, and suggests that process evaluations should explore and identify the context-mechanism-outcome relationship and to investigate the barriers and facilitators to intervention implementation.

4.4. Data Collection Methods

Beyond the conceptual foundation underpinning developmental research, those new to feasibility assessment may find it challenging to consider all possible data collection strategies that can provide useful information. Table 1 summarises a range of methods used in previous studies; they are specific to the feasibility assessment and process evaluation of complex interventions. As such, they are applicable to CAM/IM studies and should be factored into the planning of future studies.

<Insert table 1>

4.5. Checklist of Methodological Issues for Feasibility Research

The suggested framework in this section features specific domains that should be covered in developmental research. As such, it can be used to structure study design, methods, and reporting.

Shanyinde et al (2011) proposed 14 methodological points that should be addressed in the analysis of feasibility studies, based on their review of 50 randomly selected papers; see Figure 3. Bugge et al

(2013), whilst acknowledging that Shanyinde et al (2011) were not explicit about how this checklist was created, categorised it as the best available before applying it in their feasibility study.

<Insert figure 3>

4.6. Reporting Pilot & Feasibility Studies

In order to improve the transparency of papers based on clinical trials, the CONSORT statement was developed (Schulz, Altman & Moher 2010), which lists specific domains that should be included when reporting a clinical trial. Although a paper proposing an extension to the CONSORT statement for pilot and feasibility studies was published in 2016 (Eldridge, Altman & Moher 2016), it only focused on randomised studies and did not attempt to distinguish between pilot studies and feasibility studies. The authors recognised the difficulty arising from the absence of a common framework and agreed terminology.

4.7. A Process for Decision-Making After Pilot & Feasibility Trials

Following conclusion of a pilot or feasibility study, the question arises of what to do with the results. In part due to the variation in methods used, there are limited tools available to support researchers in operationalising the results of their studies. One model is recommended as a pragmatic addition to the literature.

The ADePT model – A process for Decision-making after Pilot and feasibility Trials – is a systematic method of transparent decision-making in the context of pilot trials and feasibility studies (Bugge et al 2013). It consists of three steps (see Figure 4): deciding on the type of problem experienced and evidencing each problem identified; considering a range of potential solutions and justifying them; and the assessment of the best options available. The model takes into account issues which may arise within the framework of a research study vs. those that may be more applicable to real world settings.

<Insert figure 4>

This model represents a useful and pragmatic method for guiding the decision making process following conclusion of a pilot or feasibility study and should help CAM/IM researchers to refine interventions delivered and methods used.

5. Conclusion

There is growing attention on pilot and feasibility studies but progress in this area needs to be made in the CAM/IM field. This paper briefly summarises the key literature on the topic and proposes potentially useful frameworks to evaluate feasibility, in order to achieve some consistency in methods and improve the quality of the CAM/IM evidence base.

Key Messages:

- All pilot studies are feasibility studies but not all feasibility studies are pilot studies
- Aims & objectives should always focus on feasibility concerns and include, but not exclusively focus on, outcome measure analysis
- Mixed methods, including questionnaires, focus groups, and interviews, should be used to collect feasibility data, in addition to analysing study operational data e.g. recruitment rates, attrition rates.

Conflict of Interest

There is no known conflict of interesting related to this paper.

Acknowledgements

Nil.

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Figure 1: Developing and Evaluating Complex Interventions (MRC 2008)

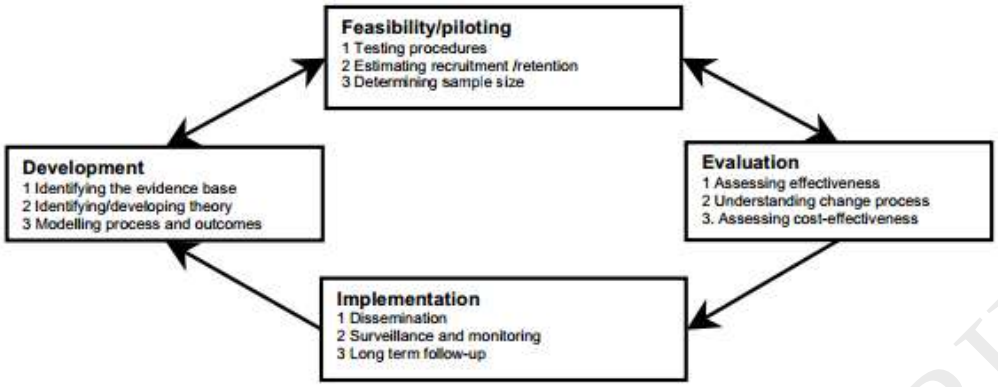

Figure 2: Proposed Logic Model for Mindfulness-Based Stress Reduction (MBSR) Effect (Donald 2016)

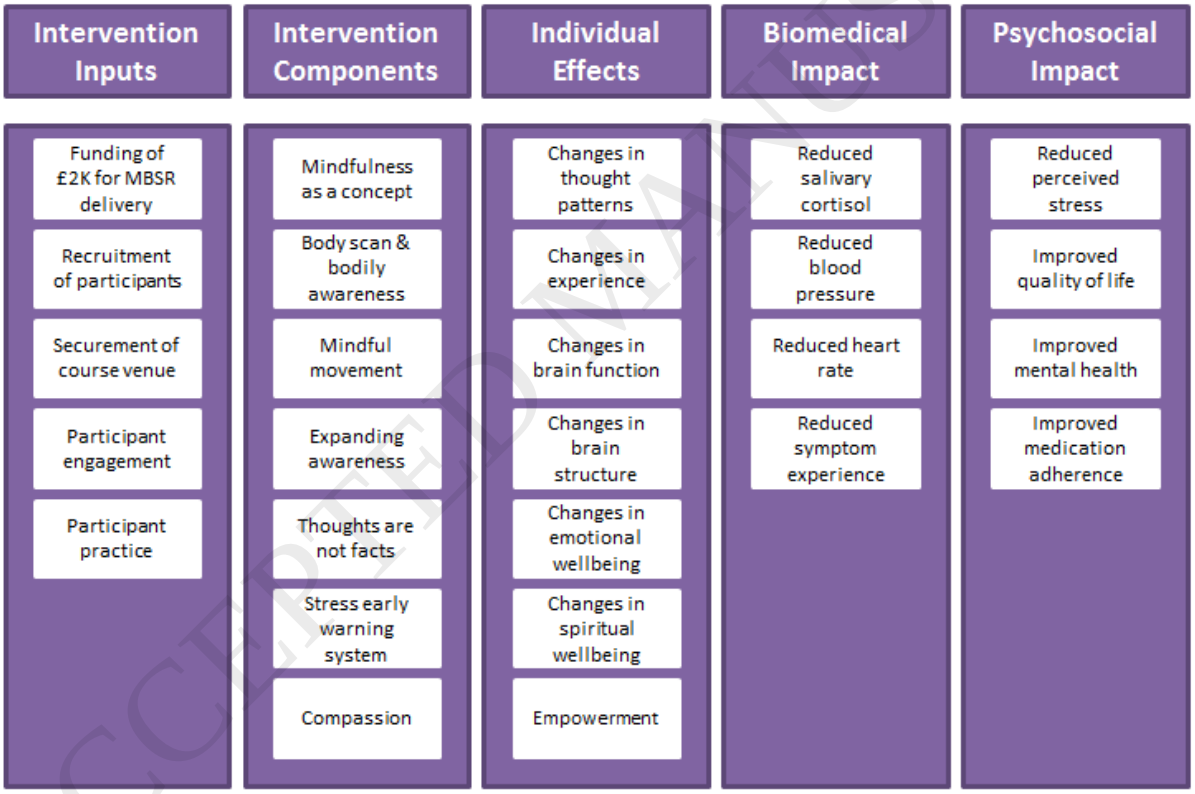

Figure 3: Checklist of Methodological Issues for Feasibility Research (Shanyinde et al 2011)

1.	Did the study allow a sample size calculation for the follow-up trial?
2.	What proportion of potential participants were eligible and what factors determined their (in)eligibility?
3.	Was recruitment successful and what were the rates?
4.	Did eligible patients consent?
5.	Were participants successfully randomised and were the final groups equal?
6.	Was blinding adequate?
7.	Did participants adhere to the intervention?
8.	Was the intervention acceptable to participants?
9.	What was the cost and duration of the intervention?
10.	Were outcome assessments completed?
11.	Were the outcomes measures acceptable, feasible and appropriate?
12.	Was retention to the study good?
13.	Were the logistics of running a multi-centre trial assessed?
14.	Did all components of the protocol work together?

Figure 4: A Process for Decision Making After Pilot & Feasibility Studies (Bugge et al 2013)

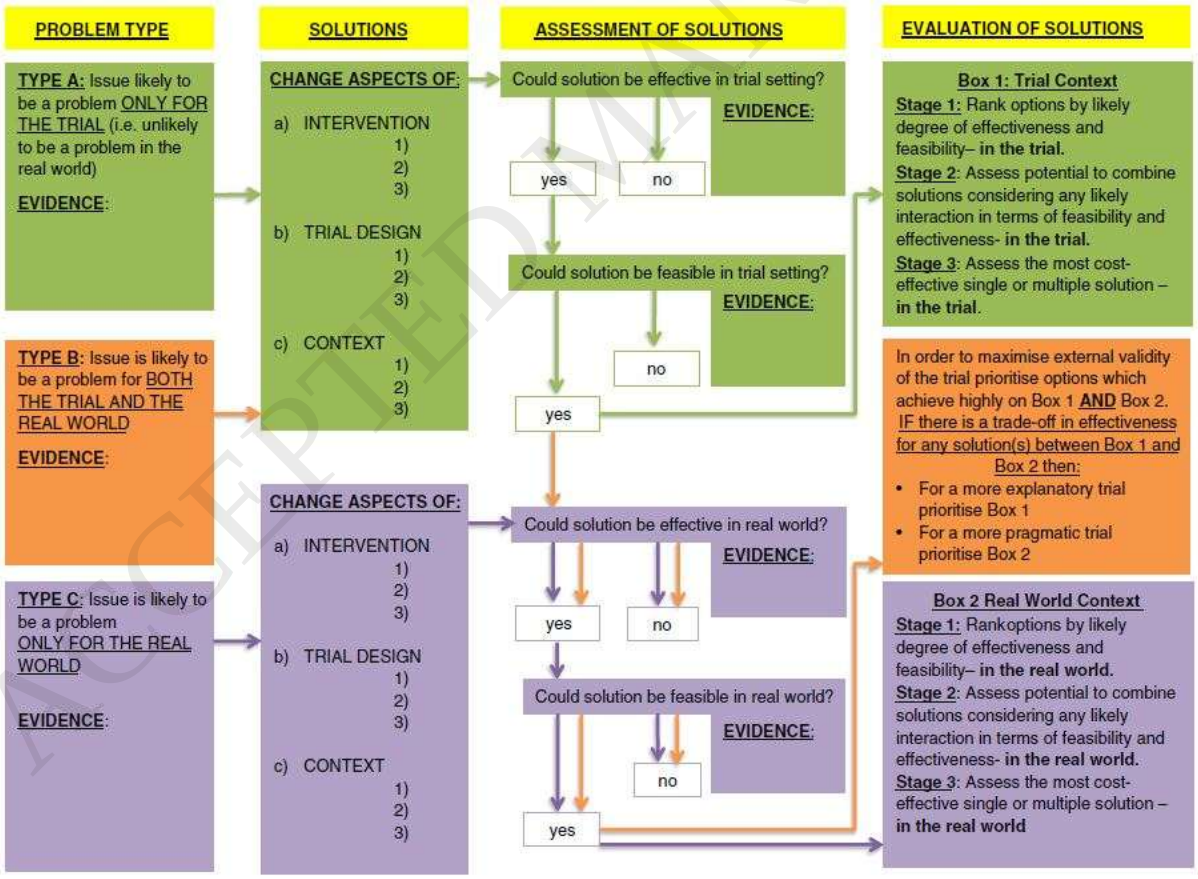

Table 1: Examples of Assessing Feasibility

	Study Aim	Methods of Data Collection
Oakley et al (2006)	To investigate whether peer delivered sex education is more effective than teacher delivered sessions at decreasing risky sexual behaviour	1. Questionnaire surveys of students and peer educators 2. Focus groups with students and peer educators 3. Interviews with teachers 4. Researcher observation of peer led and teacher led sex education
Pincus et al (2013)	To test the acceptability and credibility of a contextual cognitive behavioural therapy against best-practice physiotherapy for people with chronic back pain associated with avoidance of daily activities	1. Credibility of treatment to patients questionnaire and interview 2. Adherence statistics and patient interviews 3. Therapist interviews on acceptability and credibility of treatment 4. Feasibility of recruitment statistics 5. Outcome measure completion

Seguin et al (2018)	To determine the feasibility and acceptability of a provider-initiated, HIV self-sampling kit distribution intervention targeted at black African people in two settings	1. Acceptability questionnaire 2. Research diaries 3. Training evaluations 4. Enrolment logs 5. Distributor logs 6. Site visit notes 7. Observed data flow 8. Communications between study team and distributors 9. Site summaries 10. Close-down interviews 11. Qualitative interviews with participants