


The Distinctive Features of a Feasibility Study: Objectives and Guiding Questions

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Abstract

In this article, we highlight the distinctive features of a feasibility study, identify the main objectives and guiding questions of a feasibility study, and illustrate the use of these objectives. We synthesized the research methods literature related to feasibility studies to identify five overarching objectives of feasibility studies that focus on social and behavioral interventions. Feasibility studies are designed to answer the overarching question: Can it work? The main objectives of feasibility include the assessment of recruitment capability and resulting sample characteristics, data collection procedures and outcome measures, acceptability of the intervention and study procedures, resources and ability to manage and implement the study and intervention, and preliminary evaluation of participant responses to the intervention. For each objective, we identified follow-up questions designed to assist the researchers to understand barriers to the ultimate success of the research.

Keywords

behavioral intervention, autism, experimental design, treatment effectiveness

In the occupational therapy (OT) research methods literature, as well as the broader health and rehabilitation research literature, researchers have argued for the value of conducting feasibility and pilot research prior to conducting randomized controlled trials (RCTs; Bowen et al., 2009; Hagen, Biondo, Brasher, & Stiles, 2011; Tickle-Degnen, 2013). Researchers have recognized that intervention effectiveness research can be accelerated if careful feasibility and pilot studies are conducted prior to larger RCTs. In an important contribution to the research literature discussing the merits of feasibility and pilot studies, Tickle-Degnen (2013) provided definitions and proposed a typology of feasibility and pilot studies. In this article, we extend her ideas, but we focus specifically on the purpose of feasibility studies and provide a list of objectives and guiding questions for such a study. We describe findings from one study to illustrate how these objectives and questions can be used to guide and evaluate a feasibility study.

The British National Institute for Health Research's (NIHR) Evaluation, Trials and Studies Coordination Centre (National Institute for Health Research [NIHR], 2012) makes a distinction between feasibility and pilot studies. According to the NIHR, a feasibility study focuses on conducting research to examine whether the study can be done, whereas pilot studies are "smaller versions of the main study used to test whether the components of the main study can all work together" (NIHR, 2012). Thus, feasibility studies are conducted first, to assess the research and intervention process, followed by pilot studies, which examine the outcomes of the intervention, as implemented in a RCT, but on a smaller

scale. An important distinction between feasibility and pilot studies, especially for novel interventions, is that feasibility studies are iterative, formative, and adaptive (Bowen et al., 2009). Hagen et al. (2011) used the term *kinesthetic learning* to describe this developmental learning process. Other researchers have also noted that feasibility studies are conducted with flexible methodology, whereas pilot studies include more rigorous methodological components (Arain, Campbell, Cooper, & Lancaster, 2010).

Tickle-Degnen (2013) adapted Thabane et al.'s (2010) typology, designed for drug trials, for use in rehabilitation intervention research. Within this context, Tickle-Degnen provided definitions to clarify the distinction between feasibility and pilot studies, but her typology and guiding questions blend the purposes of feasibility and pilot studies. Blurring the distinction between pilot and feasibility studies, or using the terms interchangeably or collectively, is also observed in medical research. For example, Thabane and colleagues (2010) stated that "the main goal of pilot studies is to assess feasibility" (p. 1). Other medical researchers conducted reviews of studies published in prominent medical journals, and concluded that the methodologies used in these feasibility and pilot studies overlapped (Arain et al., 2010) and that the terms *pilot* and/or *feasibility*

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were used interchangeably in the article titles and did not reflect a distinction in the methods used (Shanyinde, Pickering, & Weatherall, 2011).

Blending the terms *feasibility* and *pilot testing* creates several problems for researchers and for those reviewing grant-funding proposals and manuscripts submitted for publication. Without clarity, researchers and reviewers may incorrectly expect rigorous examination of outcomes when the researchers' main goal was to assess the feasibility of a newly developed intervention. Often, feasibility and pilot studies are based on small sample sizes without adequate power to perform statistical hypothesis testing. If the objectives or expectations of the study are not clear, the researchers may erroneously reject evidence of intervention efficacy based on null hypothesis significance testing or judge the intervention to have poor feasibility (Arain et al., 2010; Tickle-Degen, 2013). This lack of clarity is problematic and may delay the development of innovative interventions. A significant amount of funding resources, including participants' and researchers' time, may be wasted if feasibility has not been carefully examined and assured prior to conducting a pilot study or a RCT. In addition, if the distinction between feasibility and pilot studies is blurred, researchers may strive to do too much or have incompatible goals in their research designs.

A few researchers have argued for conducting distinct feasibility studies prior to pilot studies. Gitlin (2013) and Dobkin (2009) both outline successive phases for the development and testing of novel rehabilitation and health-related behavioral interventions. In both conceptualizations, the first stage or phase appears to represent what we conceptualize as feasibility testing, with a focus on safety, learning how the intervention can be implemented, and whether the intervention is acceptable to participants. Gitlin and Dobkin argue for a progressive series of studies that will ultimately position the researchers to conduct an RCT. Throughout these preliminary studies, the researchers consider the conceptual causal model of the intervention process and the hypothesized mechanism(s) of change. Although researchers continually assess the conceptual causal model throughout the feasibility and pilot stages of intervention development, more formal evaluation of the proposed mechanisms frequently occurs in the later stages of the research continuum, after efficacy has been established.

Drawing on the emerging methodological literature, we have conceptualized feasibility and pilot studies along a continuum. Feasibility studies focus on the *process* of developing and implementing an intervention and result in preliminary examination of participant responses to the intervention (Dobkin, 2009). Pilot studies more clearly focus on outcomes, rather than process, and include a more controlled evaluation of participant responses to the intervention. Figure 1 illustrates our conceptualization of the distinctive features of a feasibility study.

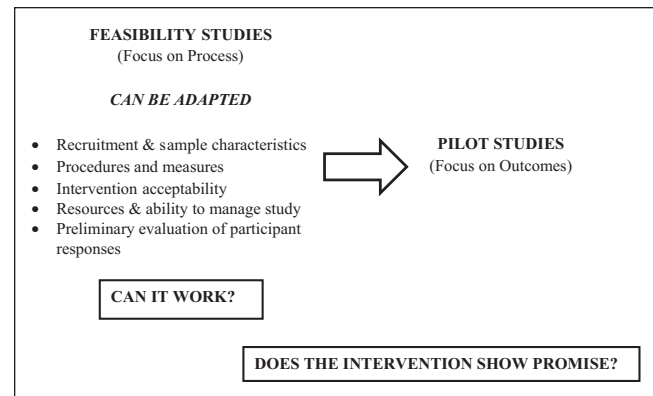


Figure 1. Distinctive features of a feasibility study.

Objectives of a Feasibility Study

Through a reflection on our experience conducting a feasibility study of a novel video-based intervention for adolescents with autism spectrum disorder (ASD) and a review of the emerging literature on feasibility and pilot studies, we identified the main objectives and questions of feasibility studies designed to answer the overarching question: Can it work? The main objectives of feasibility studies focus on the (a) evaluation of recruitment capability and resulting sample characteristics, (b) evaluation and refinement of data collection procedures and outcome measures, (c) evaluation of the acceptability and suitability of the intervention and study procedures, (d) evaluation of the resources and ability to manage and implement the study and intervention, and (e) preliminary evaluation of participant responses to intervention (see the appendix). For each objective, we identified specific follow-up questions designed to assist the researchers to understand barriers to the ultimate success of the research. The appendix provides guidance to researchers on how to frame the questions that are essential to a feasibility study. Following a feasibility study, the researchers will then need to identify strategies to address the noted challenges and/or revise components of the intervention prior to designing a pilot study to more formally evaluate intervention outcomes.

The objectives and guiding questions in the appendix were developed to guide researchers designing social and behavior interventions, including interventions with an OT focus on promoting health and participation. We conducted a literature search of Pubmed, PsycINFO, and CINAHL databases using the key words feasibility and pilot studies. We selected the manuscripts that offered a typology, proposed frameworks, guidance, or suggested questions to direct the development of pilot or feasibility studies (Arain et al., 2010; Bowen et al., 2009; Dobkin, 2009; Hagen et al., 2011; Lancaster, Dodd, & Williamson, 2004; Thabane et al., 2010; Tickle-Degen, 2013). Based on a review of these selected articles, we generated a complete listing of all recommended

questions. We then synthesized the recommendations into five main objectives for a feasibility study and categorized and revised questions for pertinence to social and behavioral intervention (presented in the appendix).

Videos of Important People (VIP) Intervention Feasibility Study as an Exemplar

Using a recently completed feasibility study, we illustrate how the appendix can be useful to researchers. We developed the VIP Intervention using principles of video-self modeling, which has been used successfully with children with ASD (Shukla-Mehta, Miller, & Callahan, 2010). The intervention reflects a strength-based approach, reinforcing positive social behaviors as they occur in natural contexts. In the intervention, adolescents create videos of their social experiences with friends; we select segments of the adolescent's videos that show the adolescent engaging in positive social behaviors. We then engage the youth in a process of positive self-review and self-reflection in an attempt to enhance the adolescent's social self-efficacy and perceived social competence. We recently completed a feasibility study of the VIP Intervention with 10 adolescents with ASD. This research was approved by the Boston University Charles River Campus Institutional Review Board. Below, we reflect on this study to illustrate how we approached and assessed the five objectives of a feasibility study outlined in the appendix.

Objective 1: Evaluation of Recruitment Capability and Resulting Sample Characteristics

The main question to ask regarding this first objective is, "Can we recruit appropriate participants?" Follow-up questions address recruitment rates, eligibility criteria, and how relevant the intervention is to the intended study population. In the feasibility study of the VIP Intervention, we proposed to collect data from 20 adolescents with ASD within 12 months. We found that it was challenging to recruit participants into the study. Ultimately, we received a 6-month extension of the grant funding, and enrolled and consented 10 participants in an 18-month period. Another participant enrolled and consented but did not begin the intervention due to personal and family challenges. Although we found that it was challenging to recruit participants into the study, the eligibility criteria were feasible and suitable. Three participants did not qualify during the phone screen (did not meet our research designated criterion for ASD, which was represented by a score of 15 or higher on the Lifetime Form of the Social Communication Questionnaire; Rutter, Bailey, & Lord, 2003). An additional nine inquiries did not result in enrollment. A frequent reason was that the adolescent with ASD did not have a friend with whom he or she could make videos.

Examining the sample characteristics is important in determining whether the intervention is relevant to the study participants. The 10 participants in the VIP Intervention feasibility study were all boys, in the age range of 12 to 16 years. There was considerable variability in their autism symptom histories and current severity of autism symptoms, although all participants had the verbal and cognitive capacities to engage in the intervention. The 10 adolescents attended a variety of public and private schools, with varying levels of inclusion with typically developing peers. Parent and adolescent reports and scores on pre-test measures of social impairments and friendship quality served as indicators that the participants were in need of the intervention. The sample members appeared to have characteristics that were consistent with what has been reported in the research literature describing youth with ASD who would be appropriate participants in the VIP Intervention. All 10 participants had documented social impairments and the language and cognitive abilities necessary to participate in the intervention. Most had co-occurring mental health conditions, which are often reported in higher functioning individuals with ASD (Simonoff et al., 2008). Six participants had a parent-reported additional diagnosis of attention-deficit hyperactivity disorder (ADHD), and five participants had a parent-reported additional diagnosis of an anxiety disorder. In addition, three participants also had an additional diagnosis of depression, bipolar disorder, or post-traumatic stress disorder (PTSD). However, variability in sample member characteristics was observed with respect to severity of autism symptoms and educational settings and services.

These data helped us evaluate the feasibility of our proposed recruitment plan and procedures. Although professional colleagues and organizations assisted with recruitment, and the materials were readily available to the intended population, few potential participants inquired about the study. There are several possible reasons for the low enrollment rates. From the local professional and research community, we are aware of the high number of researchers and research studies of ASD being conducted in the local region. This may result in fewer potential eligible members of the targeted population who are accessible because they are already enrolled in other studies. We could have chosen to adjust the research designated criterion for ASD to enroll more participants but felt this would result in a sample that would not clearly be acknowledged as having ASD by the research community. The fact that we received several inquiries about our study for potential participants who did not have a friend indicated need for an intervention focused on developing friendships; our intervention was designed to strengthen existing friendships.

Assessing our recruitment capability and resulting sample characteristics was important in determining whether the VIP Intervention and future efficacy studies would be successful. We did not anticipate that we would have such difficulty enrolling participants. We learned that a home-based

individualized intervention of the type we have designed may not be feasible. Without an additional structure (e.g., conducting the intervention within a school or clinical setting), we will likely continue to have difficulty enrolling participants at an appropriate rate in a larger pilot or efficacy study.

Objective 2: Evaluation and Refinement of Data Collection Procedures and Outcome Measures

The main question to ask regarding this objective is, “How appropriate are the data collection procedures and outcomes measures for the intended population and purpose of the study?” Follow-up questions address participants’ ability to complete the measures (e.g., comprehension, capacity), appropriateness of the amount of data collection, whether the data are relatively complete and usable, and whether the measures are appropriate for the specific population and intervention.

In the VIP Intervention feasibility study, both parents and adolescents completed written pre- and post-intervention measures that have previously been used to assess friendship and social competence in this population. Field notes, research team meeting notes, and examination of psychometric properties of the measures with this sample provided data to assess procedures and measures. Parents had no difficulty completing the measures in a timely manner and returned completed measures with very little missing data. Some adolescents needed assistance in completing the measures; some needed encouragement and supervision to complete the measures, while others benefitted from having the questions read aloud to them. The most problematic measure for adolescents to complete independently was the Social Perception Profile for Adolescents (Harter, 2012). This measure had been previously used with this population (Bauminger, Shulman, & Agam, 2004), but we observed that study participants had difficulty with the format of selecting only one response for each item to reflect their self-perception. Early in the project, we adapted this measure so that the research assistant read the items to the adolescent and assured that the measure was completed as intended. We also developed additional instructions to clarify how the response options should be used.

We examined whether the psychometric properties of the measures with our sample were consistent with what had previously been reported in the research literature with similar populations. We initially chose the measures based on the literature review and documented acceptable reliability and validity reported in prior research with adolescents with ASD. For the most part, indicators of internal consistency of the selected measures with the VIP Intervention sample were acceptable (e.g., alpha reliability coefficients above .70) and similar to what has previously been reported with samples of youths with ASD. Some of the measures, however, had low alpha reliabilities on subscales with our sample. These findings caution us when examining data at the subscale level.

These data from field notes, research team meeting notes, and examination of psychometric properties of the measures with this sample indicated to us that we have more work to do in terms of identifying appropriate outcome measures before we conduct an intervention pilot or efficacy study. Examining both quantitative (psychometric properties) and qualitative (field and research meeting notes) data with our sample was important to evaluating the extent to which the data collection procedures and outcome measures were feasible, suitable, and appropriate for use in the VIP Intervention study. We adapted the measures and data collection procedures as the project progressed; problems were discussed and noted during weekly research team meetings. Field testing the selected measures prior to the feasibility study would have been advantageous and would have helped avert some of the challenges we encountered.

The selection of outcome measures for an intervention is challenging (Coster, 2013). Oftentimes, researchers choose measures because they have been used before with similar populations or interventions. As we develop new interventions, however, we may need to develop new measures that align with the theoretical perspectives and hypothesized mechanisms of change reflected in the intervention. If researchers move too quickly to adopt an outcome measure in a RCT and the trial is not observed to be effective, it is possible that the primary problem is that the chosen outcome measure was not sensitive to change or congruent with the conceptual causal model of the intervention. Conducting feasibility assessment of measures prior to larger efforts will help researchers interpret their findings during a larger RCT.

Objective 3: Evaluation of Acceptability and Suitability of Intervention and Study Procedures

The primary question asked to address this objective is, “Are the study procedures and intervention suitable for and acceptable to participants?” Follow-up questions address retention; adherence rates to study procedures, intervention attendance, and engagement; time, capacity, and understanding of the procedures and intervention; burden; acceptability and satisfaction of the intervention to participants; and safety and unexpected adverse events. We examined the acceptability and suitability of the VIP Intervention and study procedures through qualitative feedback from parents and adolescents, and indicators of the adolescents’ engagement in the process.

We found that if a potential participant was screened and qualified for the VIP Intervention feasibility study, he was likely to enroll and participate in the intervention to completion. We observed that adolescents engaged in the intervention to varying degrees. One participant made only 28 min of video, whereas others made over 4 hr of video. We learned, however, that the VIP Intervention was not dependent on the adolescent creating large amounts of video each week. Even if a participant only made a few minutes of video in a week,

we could identify positive social behaviors to reinforce during the positive self-review sessions.

After the first few participants completed the study, we received consistent feedback from parents that the 3-week intervention protocol was too short. Parents reported that the intervention ended just as their son was engaging in the video making process. Consequently, we made a decision to increase the length of the VIP Intervention to 6 weeks. Of the 10 participants, 6 engaged in the intervention actively for 3 weeks, 1 for 2 weeks, and 3 additional participants for 6 weeks.

Acceptability of the intervention to the study participants was further assessed through parents' responses to post-intervention open-ended questions. Parents' feedback reflected their satisfaction with the approach, commenting on the benefits of focusing on their son's positive behaviors, the motivating format of intervention, the structure and support provided for video making, and the impact of positive social interactions with peers. Adolescents reported that they enjoyed using the video cameras with their friends.

Through ongoing evaluation of the acceptability and suitability of the VIP Intervention and feasibility study procedures, we adapted the intervention and dosage to better meet the needs of the participants. Initially, we limited the active intervention to 3 weeks because we believed that a longer period of time might be burdensome to families. Parents were the first to bring to our attention the need to increase the length of the intervention. Although only three participants engaged in the intervention for 6 weeks, these participants remained engaged throughout the 6 weeks. Ultimately, we found that that adolescents did not need to make as much video *each week* as we had initially anticipated. But adolescents benefitted from the positive self-review over a longer period of time.

A hallmark of the feasibility study is that the procedures and intervention can be adapted as necessary during the study to achieve the ideal and most promising format. Although other researchers have talked about feasibility studies as being iterative, kinesthetic, and adaptive (Bowen et al., 2009; Hagen et al., 2011), this may be difficult for researchers, and they may feel like their research is not progressing and the process has been slowed. Taking the time to improve the intervention and procedures before efficacy testing may, however, result in an approach that is more likely to succeed.

Objective 4: Evaluation of Resources and Ability to Manage and Implement the Study and Intervention

The main question to ask addressing this objective is, "Does the research team have the resources and ability to manage the study and intervention?" Follow-up questions address whether or not the research team has the space, administrative capacity, expertise, skills, and time to conduct the study;

ethics in implementing the study; budgetary considerations; and technology and equipment needs and training. These considerations may be most important to new investigators or researchers who are moving into a newer area of research.

In the VIP Intervention feasibility study, we did not experience difficulties with resources and the ability to manage the intervention. We had adequate space and resources from our institution. Both investigators had prior experience conducting and managing complex, multi-site research studies. The anticipated personnel needs were correct; three research assistants were responsible for collecting and entering data, delivering the intervention, and initial analysis of qualitative and quantitative data. As minor challenges arose with participant ethics (a potential breach of confidentiality in an email) and video and computer equipment, the research assistants appropriately sought out guidance and resolved the challenges efficiently and effectively. We did encounter unanticipated challenges using a new software program for the video data storage and analyses, which reinforced the need to have adequate information technology support locally and from the vendor of the software program.

Researchers will need to individually consider the extent to which it is important to formally assess resources and ability to manage a study prior to writing grants to conduct pilot studies or larger RCTs. Being able to answer the resource and study management objectives is important because grant proposals typically require a description of resources and reviewers will look for evidence that the investigator is able to manage the proposed project (Tickle-Degnen, 2013).

Objective 5: Preliminary Evaluation of Participant Responses to Intervention

The main question to address this objective is, "Does the intervention show promise of being successful with the intended population?" Follow-up questions focus on examining quantitative and qualitative data of participant responses to the intervention. Although the evaluation of intervention outcomes is more appropriate for a pilot study, during a feasibility study, the researchers need to conduct preliminary evaluation of participant response to the intervention to determine whether proceeding is advisable.

Although an in-depth discussion of the evaluation of outcomes in preliminary studies with small sample sizes is beyond the scope of this article, we provide a few cautionary statements. Many researchers conduct inferential statistics and examine effect sizes in feasibility studies, but some argue that both of these approaches are inappropriate with small sample sizes (e.g., Dobkin, 2009; Leon, Davis, & Kraemer, 2011). Although most authors acknowledge that underpowered significance tests may represent Type II errors (false negative results), few acknowledge that a Type I error is also likely (e.g., false positive results). Moreover, the use of effect sizes to justify sample size for future larger trials is also problematic (Kraemer, Mintz,

Noda, Tinklenberg, & Yesavage, 2006). Suggested alternative approaches focus on describing the variance in key outcomes and include the examination and presentation of confidence intervals (Thabane et al., 2010), examination of clinically meaningful effects (Dobkin, 2009; Leon et al., 2011), and computation of the reliable change index (Jacobson & Truax, 1991). We suggest that researchers use a combination of methods (qualitative and quantitative) that best suit their feasibility study design and measured outcomes.

To assess whether the VIP Intervention shows promise of being successful with adolescents with ASD, we examined scores on pre- and post-test measures in the VIP Intervention study and also reviewed qualitative feedback from parents and adolescents. We examined the data at the participant level and also looked for patterns of change in the variables across participants (e.g., scores changed in the expected direction). We calculated within group effect sizes for key variables. On most variables, effect sizes were small across the entire sample. We then looked at dosage effects, whether participants who engaged in the intervention for 6 weeks showed greater effects than participants who engaged in the intervention for 3 weeks. Examining these dosage effects at the participant level and with effect sizes (both between and within groups) suggested promise for the intervention for participants who engaged in the longer duration. These participants showed marked improvement on two key outcome measures.

Written comments to open-ended questions at the conclusion of the study indicated that parents observed positive changes in their son. Parents reported that their son's self-perception of their interactions with friends changed. For example, one mother said, "I was thrilled that he developed perspective on his friendships, that he was able to view himself and get feedback." Adolescents' written comments reflected learning about their strengths and the positive social behaviors we reinforced.

Examination of quantitative and qualitative outcomes from the VIP Intervention feasibility study suggested to us that the approach has promise of being successful with adolescents with ASD. We observed the most improvements on measures that were theoretically aligned with the intervention (social communication and friendship quality). Parents noted some positive changes in their son's behaviors.

As an iterative process, evaluation of participant responses to the intervention is part of a feasibility study. It is not the end point but enables the researchers to make a decision about whether to proceed with a more controlled, larger study. Within the context of a feasibility study, however, the extent to which one can examine outcomes quantitatively and calculate effect sizes will depend on study design, sample size, and how many adaptations have been made to the study protocol. Researchers may be reluctant to make changes in vivo as these changes may preclude the examination of participant responses as planned. This is one reason we recommend, as others have also done (Arain et al., 2010), that researchers focus on examining the research and

intervention process during a feasibility study, and waiting to examine preliminary efficacy in a study with appropriate design and sample size.

Discussion

In this article, we argue for the importance of carefully conducted feasibility studies. In doing so, we identify the main objectives and guiding questions of feasibility studies, and illustrate the use of these objectives through the VIP Intervention study. We reiterate that feasibility studies focus on process and are designed to answer the question, "Can it work?" and begin to evaluate whether the intervention shows promise. Feasibility studies are the initial phase of developing an intervention. Conducting a feasibility study is a developmental learning process in which the study procedures and intervention can be adapted as necessary during the study to achieve the most promising outcomes. Because adaptation is an important feature of feasibility studies, establishing fidelity to demonstrate that the intervention procedures or protocols were implemented as intended most likely occurs in the pilot stage.

The five objectives listed in the appendix are based on a synthesis of the emerging methodological literature related to feasibility and pilot studies that focus on social and behavioral interventions. These five objectives represent the essential components of a feasibility study. A concise list of focused questions to address each objective is provided to guide the feasibility phase of the intervention research process. These questions are specific to the feasibility phase and are important to address before pilot testing in more controlled designs is conducted. In addition, although other researchers have acknowledged the need to assess recruitment capability and the feasibility of eligibility criteria (Arain et al., 2010; Tickle-Degnen, 2013), we have clarified that it is important to examine whether the resulting sample is representative of the target study population. Examining the sample characteristics of recruited participants allows researchers to assess whether they have successfully accessed the population of interest. We anticipate that this synthesis and list of feasibility study objectives will be helpful to researchers in the early stages of planning an intervention study.

Similar to Gitlin's recommendations for Phase I of the randomized trial-to-translation continuum, we provide a broad conceptualization of the ways to examine feasibility and whether the intervention shows promise by identifying the need for both qualitative and quantitative data. We augment Gitlin's ideas by providing specific guiding questions for researchers to ask about both types of data. These questions acknowledge that a variety of research designs and type of data can be useful in examining whether the intervention has the potential to work.

With the increased demand for theory-driven, evidence-based interventions, there is a need for peer-reviewed publication of both feasibility and pilot studies. Moreover, funding

for the initial discovery phase of intervention research is crucial and supports the rigorous process necessary to build the foundation for successful RCTs. It is encouraging that private foundations, research-intensive universities, and profession-oriented private foundations, such as the American Occupational Therapy Foundation, offer funding mechanisms for feasibility and pilot studies. Similar to Bowen and colleagues (2009), we recommend that researchers, authors, and reviewers of grants and manuscripts be mindful of the distinctive features of a feasibility study and consider whether the focus of the project or manuscript is congruent with the appropriate phase of the intervention research.

Conclusion

In this article, we have focused specifically on the objectives of a feasibility study. By addressing the main objectives of a feasibility study and answering the questions provided, researchers will be able to assess whether they are ready or not to begin a pilot study. Although it may appear that conducting separate feasibility and pilot studies prior to launching an RCT will prolong the research process, a carefully constructed sequence of preliminary studies will ultimately accelerate the development of more effective OT and rehabilitation interventions.

Appendix

Objectives and Guiding Questions for a Feasibility Study

Objective 1: Evaluation of Recruitment Capability and Resulting Sample Characteristics.

Main Question: Can we recruit appropriate participants?

1. How many potential eligible members of the targeted population are accessible in the local community?
2. What are the recruitment rates?
 - a. How many participants enter the study at a time?
 - b. How long does it take to recruit enough participants into the study?
 - c. What are the refusal rates for participation?
3. How feasible and suitable are eligibility criteria?
 - a. Are criteria clear and sufficient or too inclusive or restrictive?
4. What are the obstacles to recruitment?
 - a. Are colleagues and local organizations willing to assist with recruitment?
 - b. What are the reasons for refusal or ineligibility?
5. How relevant is the intervention to the intended population?
 - a. Do study participants show evidence of need for the intervention?
 - b. Are the characteristics of the study participants consistent with the range of expected characteristics as informed by the research literature?

Objective 2: Evaluation and Refinement of Data Collection Procedures and Outcome Measures.

Main Question: How appropriate are the data collection procedures and outcome measures for the intended population and purpose of the study?

1. How feasible and suitable are the data collection procedures?
 - a. Do participants understand the questions and other data collection procedures?
 - b. Do they respond with missing or unusable data?
2. How feasible and suitable is the amount of data collection?
 - a. Do the participants have the capacity to complete the data collection procedures?
 - b. Does the overall data collection plan involve a reasonable amount of time or does it create a burden for the participants?
3. Do the measures appear to be performing in a consistent way with the intended population as compared to measurement information available in the research literature?
 - a. Are internal consistency indicators of measures with the recruited sample congruent with expectations based on prior studies reported in the research literature?
 - b. Do planned outcome measures appear to be sensitive to the effects of the intervention?
 - c. Does a suitable outcome measure need to be developed?

Objective 3: Evaluation of Acceptability and Suitability of Intervention and Study Procedures.

Main Question: Are study procedures and intervention suitable for and acceptable to participants?

1. What are the retention and follow-up rates as the participants move through the study and intervention?
2. What are the adherence rates to study procedures, intervention attendance, and engagement?
 - a. Does the intervention fit with the daily life activities of study participants?
 - b. Do the participants have enough time and capacity to complete the intervention?
 - c. Does the intervention involve a reasonable amount of time or does it create a burden for the participants?
 - d. To what extent is the intervention acceptable and appealing to participants?
 - e. If appropriate, how many participants agree to be randomized to group?
3. What is the level of safety of the procedures in the intervention?
 - a. Are there any unexpected adverse events?

Objective 4: Evaluation of Resources and Ability to Manage and Implement the Study and Intervention.

Main Question: Does the research team have the resources and ability to manage the study and intervention?

1. Does the research team have the administrative capacity, expertise, skills, space and time to conduct the study and intervention?
2. Can we conduct the study procedures and intervention in an ethical manner?
 - a. To what extent does staff comply with the approved human participants' protocol?

(continued)

Objective 4: (continued)

- b. How effectively are adverse events during implementation identified, documented, and reported?
3. Can the study and intervention be conducted within the designated budget?
4. Is the technology and equipment sufficient to conduct the study and intervention, including collection, management, and analysis of data?
 - a. Is equipment available when needed?
 - b. What is involved in training personal and/or participants to use the equipment?
5. Are we able to efficiently and effectively manage data entry and analysis?

Objective 5: Preliminary Evaluation of Participant Responses to Intervention.

Main Question: Does the intervention show promise of being successful with the intended population?

1. Does examination of quantitative data suggest that the intervention is likely to be successful?
 - a. Does examination of the data at the participant level suggest that changes in key outcome variables occurred?
 - b. Are the changes of the outcome variable(s) in the expected direction?
 - c. Do the estimates of effects suggest that the intervention has promise?
2. Do participants or relevant others provide qualitative feedback that may be indicative of the likelihood that the intervention will be successful?
3. If the quantitative and/or qualitative data suggest that the intervention is not promising:
 - a. Are the data collection procedures and outcome measures appropriate for the population and study?
 - b. Are the outcome measures and intervention theoretically aligned?
 - c. Is there evidence that the intervention does not produce change in the desired outcomes?
 - d. Is there evidence that the intervention was not implemented in the intended manner?
 - e. Have too many adaptations been made in the intervention process to adequately assess the participants' responses to the intervention?
 - b. Are the findings congruent with the proposed theoretical model for the intervention?

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