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Instrument Selection for Randomized Controlled Trials Why This and Not That?

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Abstract

A fundamental linchpin for obtaining rigorous findings in quantitative research involves the selection of survey instruments. Psychometric recommendations are available for the processes for scale development and testing and guidance for selection of established scales. These processes are necessary to address the validity link between the phenomena under investigation, the empirical measures and, ultimately, the theoretical ties between these and the world views of the participants. Detailed information is most often provided about study design and protocols, but far less frequently is a detailed theoretical explanation provided for why specific instruments are chosen. Guidance to inform choices is often difficult to find when scales are needed for specific cultural, ethnic, or racial groups. This paper details the rationale underlying instrument selection for measurement of the major processes (intervention, mediator and moderator variables, outcome variables) in an ongoing study of postpartum Latinas, *Madres para la Salud* [Mothers for Health]. The rationale underpinning our choices includes a discussion of alternatives, when appropriate. These exemplars may provide direction for other intervention researchers who are working with specific cultural, racial, or ethnic groups or for other investigators who are seeking to select the 'best' instrument. Thoughtful consideration of measurement and articulation of the rationale underlying our choices facilitates the maintenance of rigor within the study design and improves our ability to assess study outcomes.

Keywords

instrument; reliability; validity; intervention; randomized controlled trials

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Introduction

Rigorous findings that contribute to the scientific knowledge base to improve the health status of individuals, groups, and communities are the ultimate goals of quantitative research. A fundamental linchpin for obtaining rigorous findings involves operationalizing study concepts though the selection of survey instruments. For over three decades, psychometricians have led researchers through the processes for scale development and testing when empirical indices were inadequate or absent in particular construct domains, and have provided guidance for selection of established scales. These processes include descriptions of domain identification, integration of expert critique, and the statistical methods by which one evaluates linkages between the identified constructs, concepts, and their empirical indicators (most often described as various types of validity), and the psychometric criteria for estimating reliability.

Detailed guidance for selection of scales for that are applicable to specific cultural, ethnic, or racial groups or explanations is more difficult to ascertain. Researchers may rely on translation and back-translation procedures as evidence of the appropriateness of the selected instruments and may provide an evaluation of equivalence. These processes are well accepted, but also have inherent limitations – recently addressed in the literature.[1, 2] In addition, burden and reading level are taken in to consideration. Further, accessibility, appropriateness for clinical practice, and the investigator's prior experiences with an instrument are pragmatic concerns that effect instrument selection.

These processes are all necessary, but not sufficient, to address the validity link between the phenomena under investigation and the empirical measures and in turn, the theoretical ties between these and the world views of the participants. Detailed information is most often provided about study design and protocols, but far less frequently is a detailed theoretical explanation provided for why specific instruments are chosen. This explanation is even more important to include when the intervention involves vulnerable groups, participants from diverse groups, or collection of data from subjects living in politically charged environments.[2] The purpose of this paper is to detail the rationale underlying instrument selection for measurement of the major processes (intervention, mediator and moderator variables, outcome variables) in an ongoing study, *Madres para la Salud* [Mothers for Health] (see Keller et al.[3] p. 420, Figure 1). These exemplars may provide direction for other intervention researchers who are working with specific cultural, racial, or ethnic groups.

Exemplar: Madres para la Salud

Madres para la Salud is a randomized controlled trial with postpartum Latinas living in the Southwestern United States to test the effectiveness of a social support and walking intervention at effecting changes in body composition (body fat, systemic and fat tissue inflammation) and depressive symptoms. One moderator and one mediator are considered: environmental factors moderate the effect of the intervention by influencing the number of minutes walked per week, while the dose-response of walking mediates the effect of the intervention on the outcomes.

The participants in the study are urban Latinas who: (a) are between the ages of 18 and 45 years, (b) gave birth less than six months prior to enrollment, (c) are sedentary and overweight, and (d) are without plans to become pregnant within the next year. After recruitment, screening, informed consent, and random assignment to the intervention or attention control group, the 12-week intervention is implemented, and all women are followed for 48 months. For additional about the design of the study, please see Keller et al.[3] Thus, the instruments selected for use in this study needed to be appropriate for young

Latinas who were literate in either Spanish or English, balance burden considerations with accuracy and specificity, and strongly link to the conceptualization of each construct.

Social Support Conceptualization and Measurement

Social support is the active ingredient of the Madres intervention. There is strong evidence supporting the relationship between social support and physical activity[4–7] particularly for Latinas.[8–11] Similarly, there is consensus that social support is essential to physical activity among Mexican-born Hispanic women across settings[6] and life stages.[12–16] In spite of the strong evidence that exists for the significance of social support to physical activities among Latinas, less agreement exists at the conceptual level.

Conceptual definitions of social support vary greatly. Examples of social support definitions include: (a) number of people living in the household (a proxy indicator based on the premise that those living in close proximity provide support), (b) network size (number of people in one reports in his or her close circle of friends and family), (c) availability of supportive others, including the supportive behaviors that are needed and one's perceived receipt of the degree to which his or her needs are met, and (d) categorizations of various types of social support. The conceptual definition of social support used in Madres para la Salud includes the four dimensions proposed by Heany and Israel:[17] emotional, instrumental, appraisal, and informational. This definition is congruent with findings in the literature of how Latina women view support within their families and communities.[18]

The Medical Outcomes Study (MOS) Social Support Survey[19] is a close match to the conceptual definition chosen for Madres. The MOS measures participants' perceptions of four dimensions of support: affection, emotional/informational, positive social interaction, and tangible support. This instrument allows examination of changes in any or all of the dimensions of social support over the 48 week intervention. It may be that informational support is most helpful at the beginning of a physical activity intervention, but over time, other dimensions increase in importance. This instrument is a good choice for mothers who, in many cases, have more than one child because it is relatively brief, consisting of 19 Likert-type questions with 5-point response options ("1 = none of the time" to "5 = all of the time). Reliability coefficients are acceptable >.83 in both English and Spanish-speaking samples.[20]

Selection and Rationale for Moderator Measurement

The moderator in the Madres study is the environments in which participants walk. Access to safe, affordable facilities is an important influence on adherence, particularly among the elderly and poor. Eyler and colleagues[21] showed that an unsafe environment, lack of available and appropriate programs, and high costs were barriers to walking. In one study, factors associated with inactivity included the observation that others infrequently engaged in physical activity.[22] Recent work indicates that women who perceive their neighborhoods as unsafe are more likely to be obese.[23]

There are various ways to conceptually define the environment. Socioeconomic status is sometimes used as a proxy that represents the degree to safety and amenities exist within a defined area, often delineated by zip codes. More specific ratings of environment are obtained from participant's ratings of characteristics of the physical environment, such as attractiveness, available amenities, safety, and community engagement activities.[24] Other researchers have used photographs to elicit participants' preferences for an ideal setting in which to walk.[25] A clear differentiation between the physical environment and the social environment appears in many studies of this concept.[24, 26]

A primary consideration when selecting the measurement indice for environment for the Madres study was the plan to implement the intervention with postpartum Latina mothers living in very poor neighborhoods. Thus, the ideal instrument would assess the key domains of physical and social environments so that a full range of moderator effects could be examined. The Neighborhood Environment Questionnaire was selected because it measures the key domains of perceived safety of the walking environment and available resources for walking[27] while also assessing social and cultural perceptions of participants related to their neighborhoods. The 38-item scale assesses the multiple dimensions of environment with the following subscales: walking environment (e.g., available shade, traffic; n = 10 items), aesthetic qualities (e.g., noise, attractiveness; n = 6 items), availability of healthy food (e.g., fresh, low-fat, or fast food availability; n = 4 items), safety (e.g., crime; n = 3), social cohesion (e.g., community activities and belongingness; n = 3 items), violence (4 items), and neighborhood activities (5 items). All items are rated on a 5-point scale ("0 = strongly disagree" to "5 = strongly agree") with the exception of the last two subscales. The violence and neighborhood activities subscales are rated with 4 response options ("0 = often" to "4 = never"). Test-retest reliability for the environmental resources scale is .80. The validity of the scale was evaluated through correlations with self-report physical activity.[27]

Selection and Rationale for Mediator Measurement

Walking was selected as the mediator variable because of the abundant evidence indicating that it is the physical activity of choice, across generations, ethnicity, and conditions.[28] Walking is the physical activity that is most easily integrated in to the daily lives of our participants and these young Latina mothers can have family members accompany them on their planned walks. Mothers may walk their children to school, to the playground or friends' houses, or around the neighborhood. Similarly, sisters, aunts, and husbands can be invited to share walk time, thereby increasing the likelihood that walking will continue throughout the duration of the study and beyond. While walking activity has been studied extensively in randomized controlled trials, far fewer studies examine the dose of walking that contributes to positive outcomes and often rely on physical activity recommendations for the minimum number of minutes and intensity of 'dose' per week. In the Madres study, analyses will attempt to unravel the walking dose that results in optimal outcomes.

The complexity of the domain of walking and the intensive requirements for recording participants' physical activity needed for accurate outcomes was addressed by using multiple survey and objective measures.[29] Walking was conceptualized as daily and weekly walking and included pedometer-recorded step counts and minutes walked at moderate intensity, accelerometer activity counts, and intensity, duration, and types of self-reported activity performed on walking calendars, physical activity questionnaires, and physical activity records. Multiple assessment methods were needed to fully explain (a) compliance to the walking intervention, (b) changes in daily physical activity associated with participation in the research study, and (c) associations between walking volumes and changes in the psychological and physiological outcomes measured in Madres para la Salud.

Walking was recorded with various measures to capture the context and volume of walking during the study. We used pedometers to identify the volume of daily steps walked and the minutes of the walking at a moderate pace. An additional indicator for participation was to record the daily steps taken on a walking calendar. To assess if the walking intervention caused increases in lifestyle activity incidental to the prescribed dose of walking exercise, an accelerometer was worn periodically to record the frequency and duration of movement ranging from no movement (sedentary behaviors) to vigorous-intensity movement. A physical activity diary also was completed while accelerometers were worn to record and/or recall changes in the type, frequency, and duration of lifestyle activities during the study. A physical activity questionnaire was completed at the beginning and end of the study to

classify the participants' self-reported leisure-time and occupational physical activity levels. Each of these methods is described more fully, below.

Pedometers—The Madres protocol includes the use of pedometers, specifically the Omron (model HJ-720ITC), a small, lightweight electronic device that provides an objective, nonintrusive estimate of walking levels in an adult population.[30, 31] The Omron pedometer can be worn on the waist or in a pocket. Pedometers are documented as an optimal objective monitor for use in research settings to provide feedback to participants regarding their daily walking goals,[32] to assess changes in study outcome measures associated with the volume of walking,[33] and to provide an indicator of compliance for study participation. We selected the Omron pedometer to monitor the volume of daily walking over other pedometer models because it recorded daily steps taken for seven days, allowed for data to be downloaded to a computer, and also identified the minutes of walking at a cadence associated with moderate-intensity exercise (i.e., < 100 steps per minute).[34] This provided direct feedback to participants about their daily walking goals and allowed them to moderate their walking speed to assure they were accumulating at least 30 minutes of moderate-intensity walking speed. The 30 minute walking dose could be split into 10-minute bouts completed at three different times of the day as identified by the 1995 and 2007 public health recommendations about the volume of physical activity associated with health enhancement and chronic disease risk reduction.[35, 36] Having a pedometer that records the daily steps taken allows the study investigators to assess compliance to the study protocol while also providing another source of data.

We could have used a wrist watch with a stopwatch function to record the duration of walking, but felt that would be more difficult for participants to remember turning the stopwatch function on and off and remember to record the duration after the walking session. Plus, only recording the duration of intentional walking as prescribed by the study protocol does not allow for identification of changes in daily ambulatory activity that may result as a consequent to study participation. Similarly, we discounted the option to record the intensity of exercise using a heart monitor worn with a chest strap or a wrist watch because we felt that compliance to this method would be poor and that easier methods were available in the use of the Omron pedometer that counted steps per minutes (cadence) as an indicator of intensity. Thus, because of the ease of viewing steps taken during a period of time and on a daily basis, we selected pedometers to record walking behaviors instead of recording the minutes of walking.[32] Accumulated evidence supports the use of pedometers as valid walking assessment tools.[33] To characterize physical activity behaviors with at least 80% reliability, Tudor-Locke[37, 38] determined that subjects needed to wear the pedometer continuously for 3–4 days to characterize moderate and vigorous activity patterns and for 7 days to characterize physical inactivity behaviors.

Activity Calendars—Daily step counts and minutes walked at moderate intensity are self-reported on an Activity Calendar as the number of 10 minute bouts of moderate-intensity walking/day and length, in minutes, of the bouts. Walking volume is calculated by minutes walked per day for each minimum 10-minute bout, and summed for a weekly total. Recording health behaviors on a calendar or in record book is associated with increased compliance with a behavior change.[39] The walking calendar also is used to monitor compliance to the study walking protocol. Promotoras collect the Activity Calendars weekly and record each participant's weekly totals.

Accelerometers—Validation of walking frequency, duration, and intensity is obtained using an ActiGraph GT1M accelerometer – a small, battery operated electronic motion sensor designed to measure the rate and magnitude of bodily movement, validate physical activity questionnaires, and quantify associations between physical activity behaviors and

health outcomes.[40] The ActiGraph accelerometer outputs data as counts that reflect: (a) the intensity of movement as reflected by the frequency of deflections and (b) the duration as the sustained period of the deflections. Cut-points developed from controlled laboratory experiments use the accelerometer count data to estimate the minutes of activity at various intensity levels.[41–43] The Matthews[44] and Freedson[41] cut-points are used to classify activity levels by intensity and are: sedentary (< 100), light, 1.5 – 2.9 METs (100–1951 counts); moderate, 3.0–5.9 METs (1952–5724 counts); and vigorous, ≥ 6.0 METs (≥ 5725 counts).

The ActiGraph is programmed to capture accelerations at 30-second epochs beginning at midnight of the day the instrument is initialized. The ActiGraph activity monitor data, recorded as counts, are directly downloaded into a computer as an electronic data file. Prior to data analyses, monitor data for each subject is scanned and removed if (a) accelerometer data indicates less than 10 hours per day of movement counts and (b) there is no indication of lower levels of activity on the activity calendar to eliminate inclusion of data from subjects who were not compliant with the study protocol. The activity (mean over 3–7 days) is translated into free-living physical activity (minutes per day at light, moderate, hard, and very hard activity) using the software supplied with the program.

To characterize physical activity behaviors with at least 80% reliability, Matthews[44] determined that subjects needed to wear the ActiGraph on a belt around the waist continuously for 3–4 days to characterize moderate and vigorous activity patterns and for 7 days to characterize physical inactivity behaviors. Following Matthews recommendations regarding capture of physical inactivity, the Madres' participants wear the ActiGraph for 7 days at a time at five time points.

We chose to use the ActiGraph GT1M accelerometer over other accelerometer models (e.g., Actical, Sensewear) because of the use of the ActiGraph accelerometer in intervention research studies,[45] NHANES surveillance settings,[44, 46–48] and the research showing associations between ActiGraph accelerometer scores with chronic disease risk factors,[49] including body composition.[48] Also, studies examining the use of the ActiGraph accelerometer have shown it is feasible to have women, similar to those in this study, wear the monitor from 3–7 days for at least 10 hours/day as required for this study.

Physical Activity Record—We used a one-week self-administered physical activity record and/or a 3-day interviewer-administered physical activity recall to identify the type, frequency, duration, and intensity of daily physical activities performed during the same period when the ActiGraph accelerometers were worn. The physical activity record was used to identify changes in the types and intensities of physical activities performed incidental to the intentional walking intervention. The physical activity record was modeled after the children's 3-day Physical Activity Recall (3DPAR)[50] that has respondents identify their primary activity performed every 30 minutes. Instead of have a pre-determined list of activities for respondents to select, participants write the primary activity such as cooking, watching television, child care, etc. They identify their body position during the activity (reclining, sitting, standing, or walking) and their perceived effort (light, moderate, or vigorous).

We selected a modification of the 3DPAR to record the types of daily physical activity performed instead of other measures because of the ease of completing the activity. Ideally, we wanted to following the procedures used in the Cross-Cultural Activity Participation Study[51] and the Survey of Activity, Fitness, and Exercise study[52] where participants completed detailed 4 to 7 day physical activity records and recorded every activity as it was performed during the day. A typical day of recording produced from 60 to 300 activities recorded. However, in a pilot study, we found this procedure was time consuming for the

participants and it resulted in low compliance for completing the records. Thus, we found a simpler method that would yield similar information about the primary types of physical activities performed during the day and that would allow us to link the movement data recorded by the ActiGraph accelerometer. Some participants were able to complete their own records every 30 minutes. For others who were unable to complete the records as the activities were performed, trained interviewers administered a 3-day recall of primary activities performed every 30 minutes.

The physical activity records were translated from Spanish into English by bi-lingual study personnel as needed, and scored using the 2011 Compendium of Physical Activities[53] to link the activity recorded with a 5-digit activity code and its associated MET intensity. The number of 30-minute bouts for the types and MET intensities of activities are recorded for data analysis.

Physical Activity Questionnaire—The Stanford Brief Activity Survey (SBAS) was administered to obtain a self-report of the participants' levels of leisure and occupational physical activity. The questionnaire provides five written scenarios for the types of activities performed in each setting ranging from sedentary to vigorous activity levels. The questionnaire is scored using an algorithm developed to link profiles of leisure and occupational activity to rate activity levels as inactive, low active, active, high active, very high active.[54] The questionnaire was translated into Spanish and self-completed in Spanish or English language as needed.

We chose the SBAS to identify self-reported levels of physical activity because it is a short survey, takes little time to complete, and does not rely on the recall of time spent in various types of physical activities. It also is shown to have a strong, dose-response relation with the prevalence of metabolic syndrome and with factors associated with metabolic syndrome (e.g., systolic blood pressure, fasting glucose and insulin, etc.).[54] Thus, we felt this simple instrument would be a good measure of physical activity to assess the current activity levels at the start of the study and to assess if the ratings of physical activity changed during the study.

Selection and Rationale for Outcome Measurements

Body fat loss—Overweight and obesity are prevalent among the Hispanic population, and even more so for Hispanic women during the childbearing years. Some estimates indicate that >70% of Hispanic women are overweight or obese, and many of these women have concomitant sedentary lifestyles. Therefore, a key outcome for this intervention study had to focus on the outcome variable of body fat loss.[55]

Investigators have many choices for measurement of body fat loss, including skinfold calipers, bioelectrical impedance, a Bod Pod, and or hydrostatic weighing among others. Selection of the best measurement is dependent on factors such as subject burden concerns, study budget, and the availability of resources for measurement at the study site(s). Body fat loss is measured in the Madres study using two methods. Each method compares baseline body fat percentage to subsequent time points; however one method is feasible for use in community and home settings while the second method requires specialized equipment. All participants receive the measurement(s) that can be conducted in community and home settings. A subset of participants receive the gold standard measurement, thereby limiting costs for the test and reducing transportation issues for subjects to the site with the equipment. An added benefit of this approach is that we can estimate concordance between the two methods and add to the science of body fat measurement.

At five time points for all participants, body fat is estimated from height, weight, age, gender, race/ethnicity, smoking status, and activity level using the equations reported by Fernandez et al.[56] and Jackson et al.[57] Weight is measured to the nearest 0.1kg using (a) a digital scale that is calibrated prior to each use, (b) the average of three successive measures, (c) with the participants clothed but shoeless. Height is measured with a standard measuring tape and by taking the average of two successive measurements to the nearest 0.5 cm. Participants are shoeless and standing erect on an uncarpeted floor with heels placed as close as is comfortable to a doorframe.

The second method for estimating body fat involves using state-of-the-art dual energy x-ray absorptiometry (DEXA screenings) at the beginning and end of the study for a subsample of the intervention group. Correlation coefficients between percent body fat and DEXA scans range from .69 to .91.[58, 59] DEXA scans use a dual energy x-ray beam to measure whole body lean and fat content, it is considered the gold standard for clinical measurement of bone mineral density (BMD).[60] The DEXA scanner available is a Lunar Prodigy with version 6.1 imaging software. It has lower precision error than dual photon absorptiometry (<1.0%) and requires shorter exam time with less radiation exposure.[61] The cumulative dose of radiation for both a total body and lumbar scan is 10.0 mrem, significantly less than for computed tomography. The total body scan takes approximately 5 minutes. The software program that accompanies the scanner allows for direct comparison of previous scans and provides automatic calculation of visit-to-visit changes in body fat. A licensed and certified densitometry technologist performs all scans, compares changes over time, and interprets results. Quality assurance data will be collected with a linearity phantom, the machine's calibration standard, to establish instrument cross-calibration.

Systemic and fat tissue inflammation—Our research team was committed to increasing the scientific knowledge base for physical activity by examining the physiologic mechanisms that, unabated, contribute to rising morbidity and mortality rates secondary to obesity. To do this, we examined the literature to identify the indicators that are most likely to respond positively to physical activity and that are also linked to the other study outcomes. As the pro- and anti-inflammatory factors that were most strongly correlated with physical activity, body composition, and depressive symptoms were identified (see Keller and colleagues),[3] the team wrestled with the pragmatic concerns such as laboratory capabilities, participant burden, participant retention, and study costs. Based on these concerns, a two-pronged approach was chosen for measurement of interleukin-6 (IL-6), IL-8, tumor necrosis factor alpha, and C-reactive protein (CRP).

The two-pronged approach included collecting blood and fat tissue for analysis of inflammatory factors at baseline and the end of the study (48 weeks). Key factors in deciding what time points to use and how many time points to include were participant burden and study costs. Further, there is not sufficient evidence at this time to allow us to identify the best time measurement window. For example, it is unknown how many weeks at a specific intensity of activity result in significant clinical differences in inflammation levels. A final cost consideration was handled by having a randomly selected subset of participants (n = 22) undergo data collection for blood and fat tissue. Costs for this subset included fees for blood draws, the fat biopsies, transportation for participants to the study site, study personnel to accompany participants during the biopsy, transportation of samples to the laboratory, as well as laboratory staff and supplies.

At the same time points, a small subcutaneous fat tissue sample from the abdominal area is obtained from consenting subjects using the standard incisional biopsy method.[62] The mRNA expression levels of IL-6, IL-8, PAI-1 as well as TNF- in the tissue are determined using Real Time PCR. Another portion of the fat tissue sample is cultured ex-vivo using an

established procedure.[63] At the end of the incubation period, media conditioned by the tissue is collected to determine the concentrations of IL-6 and IL-8, secreted by the tissue. The first three proteins are determined using methods described above. TNF- is determined using an ELISA kit (R&D Systems) with CV ranges of 4–5% for intra-assay precision and 4–7% for inter-assay precision; although new developments have occurred in the analysis processes for TNF-α, ELISA provides results with good reproducibility and high sensitivity.[64]

Postpartum depression symptoms—Depression is experienced by 12% of new mothers and rates of depression after birth are significantly higher for Hispanic as compared with Caucasian non-Hispanic samples. Rates of depression among Hispanic mothers have been reported as approaching 43%.[65, 66] Depression has many consequences for new mothers and their infants, but is especially problematic as symptoms interfere with the desire of mothers to participate in physical activities,[67] even though physical activity can sometimes be helpful in lessening or resolving depression symptoms. In addition, researchers have found relationships between depression symptoms, weight accumulation, and activation of the inflammatory response (e.g., expanded adipose tissue releasing interleukin-6 [IL-6]).[68] Recent findings indicate that inflammation may be the most significant risk factor for depression.[69] Consistent elevations in IL-6, interleukin-1beta (IL-1beta), and TNF- are apparent in depressed individuals, and may be linked to postpartum depression through fatigue (e.g. IL-1 beta).[70]

Several issues were taken in to consideration as a depression measurement indice was chosen. Measurement of depressive symptoms was preferable to a diagnostic test for depression for a number of reasons, including (a) subject burden when considering the study's instruments as a whole, (b) greater acceptability for screening as compared with diagnosis among these participants, (c) availability in Spanish and English because many of our participants are monolingual Spanish-speakers, and (d) a scale that is easily scored on-site and immediately after completion to facilitate referral to appropriate resources for women with high scores or suicidal ideation. Although a number of instruments were considered, the Edinburgh Postnatal Depression Scale was chosen. In addition to the factors cited above, the EPDS was familiar to many of the participants through depression symptom screening in prenatal care.

The 10-items of the EPDS assess a woman's feelings of sadness and hopelessness in the past seven days. Each item has four response options (scored 0 to 3) and total scores range from 0 to 30, with higher scores indicating more severe depressive symptoms. Although there is some variation in the cut scores used for particular samples, we chose to use the commonly accepted cut points of >12 as likely indicative of depression and scores >14 as indicative of major depression. The EPDS has robust psychometrics, including: (a) its validation in numerous clinical studies with postpartum women, (b) sensitivity of >0.60 – 0.96 for major depression (specificity > 0.97 to 0.45, respectively) and 0.31 – 0.91 for major or minor depression (specificity 0.99 – 0.67, respectively),[71, 7273] (c) Cronbach's alphas of .77 to .87,[74, 7576] and (d) the availability of Spanish-language versions.[77,78] Further, the EPDS is extensively studied and performs well against seven other self-report depression symptom measures and is particularly well-suited to administration in clinic and non-clinic settings.[73, 79]

Conclusion

Description of the validity linkages and theoretical ties to the worldviews and real lives of Madres' participants provides an exemplar for intervention researchers. Decisions regarding study design, selection of study instruments, and implementation of the data collection procedures can be fraught with challenges. A priori consideration of the needs of the

participants and the theoretical underpinnings of the concepts of choice will provide guidance for researchers. Clear articulation of the choices and the rationale for these choices facilitates the maintenance of rigor within the study design and improves our ability to assess study outcomes.

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