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A Postpartum Sleep and Fatigue Intervention Feasibility Pilot Study

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Introduction

Postpartum sleep and fatigue are two of the most pressing and persistent issues mothers struggle with daily in the months after childbirth. Postpartum women sleep an average of seven hours each night; however, sleep efficiency is lower than in non-postpartum populations due to nocturnal infant caregiving (Filtiness, MacKenzie, & Armstrong, 2014; Gay, Lee, & Lee, 2004; Montgomery-Downs, Insana, Clegg-Kraynok, & Mancini, 2010). Sleep efficiency, or the percentage of time spent asleep relative to the time spent in bed, is lowest shortly after birth and improves slowly over several months as the infant's sleep consolidates and the infant's daytime sleep shifts to nocturnal hours (Filtiness et al., 2014; Montgomery-Downs et al., 2010). Postpartum fatigue, conceptualized as having both physical and mental dimensions (Parks, Lenz, Milligan, & Han, 1999), is highest in the days after giving birth and tends to follow one of two trajectories; either improving quickly over the first postpartum weeks or remaining high for several months (Doering Runquist, Morin, & Stetzer, 2009; Gardner, 1991; Rychnovsky & Beck, 2006; Troy, 1999). The health effects of poor subjective sleep, and postpartum fatigue on mothers and their families are numerous, including depression, early weaning from breastfeeding, poor functional status, and impaired infant development, and are often overlooked by health care providers (Coo, Milgrom, & Trinder, 2014; Dennis & Ross, 2005; Doering Runquist et al., 2009; Goyal, Gay, & Lee, 2009; McVeigh, 2000; Parks et al., 1999; Rychnovsky & Hunter, 2009; Troy, 2003).

Children and adults living in socioeconomic disadvantage (SED) have greater prevalence of sleep disorders and overall, have lower sleep quality and quantity (Friedman et al., 2007; Mezick et al., 2008; Moore et al., 2011; Moore, Adler, Williams, & Jackson, 2002; Spilsbury et al., 2006). Evidence is beginning to suggest that postpartum women living in SED are more vulnerable to difficulties with sleep and fatigue (Doering & Durfor, 2010; Doering Runquist et al., 2009). The sleep environment is one important contributor to poorer sleep in postpartum women living in SED (Doering, 2012). The significance of the sleep environment is also documented in non-postpartum populations of SED (Mezick et al., 2008), and sleep quality is specifically implicated as a partial mediator between disadvantaged neighborhoods and the lower physical and mental health seen in this population (Hale et al., 2013). Improving health through sleep in populations of SED is a complex and multifaceted issue, which further stresses the need for effective and innovative

interventions. Furthermore, interventions to improve sleep in postpartum women may have cost-effective preventive and treatment benefits for maternal mental health outcomes (Grosse, Teutsch, & Haddix, 2007; Lawson, Murphy, Sloan, Uleryk, & Dalfen, 2015). The purpose of this study was to evaluate the feasibility, acceptability, and cost of a self-management intervention for postpartum fatigue and sleep in socioeconomically disadvantaged urban women.

Interventions for Postpartum Sleep and Fatigue

The published interventions to date that attempt to improve sleep or fatigue in postpartum women have demonstrated mixed results. Lee and Gay's (2011) intervention to improve maternal sleep through an intervention that improved the bedroom environment, benefited primiparous mothers living in SED more than a non-disadvantaged sample. Stremmler et al.'s (2013) double-blinded randomized controlled trial of a behavioural-educational intervention, delivered inpatient postpartum and reinforced in follow-up phone calls, did not demonstrate improvements in maternal or infant sleep over usual care at 6 and 12 weeks postpartum. A nurse-led phone intervention in Iceland that aimed to reduce fatigue and symptom distress in postpartum mothers who reported depression symptoms and difficult infants showed some initial efficacy, but has not since been replicated (Thorne & Adler, 1999). In Australia, an efficacy trial was conducted of the Wide Awake Parenting intervention, a professionally-led and self-directed telephone support fatigue management program. Infants of mothers in the study were on average 3 to 4 months and the experimental condition demonstrated improved outcomes as measured by engagement in health and self-care behaviors (Giallo, Cooklin, Dunning, & Seymour, 2014).

Theoretical Framework and HUGS Intervention Development

The Individual and Family Self-Management Theory (IFSMT) guided development of the treatment condition (Ryan & Sawin, 2009). Although self-management has traditionally been applied primarily to chronic illness, this theory expands self-management into the realm of health promotion (Ryan & Sawin, 2009). Helping U Get Sleep (HUGS) is a theory-driven, evidence-based intervention constructed to promote sleep and reduce fatigue in postpartum women in the early postpartum. The HUGS intervention components were developed using the process of self-management as identified in the IFSMT and applied to postpartum fatigue and sleep (Doering, 2013). To summarize the IFSMT, the process of self-management includes the broad categories of knowledge and beliefs, self-regulation skills and abilities, and social facilitation, which all have sub-components addressed by the intervention.

While the HUGS intervention includes education on knowledge and beliefs about sleep and fatigue, the intervention differs from existing interventions by including the self-management behaviors of goal setting, action planning and evaluation. The intervention also takes into account the physical and social context in which each woman lives. Goals and actions are client-driven, and a professional nurse facilitates the client to learn how to engage in self-management, in part, through a repeated process of evaluating the client-initiated goals and the actions taken to achieve those goals. More specifically, during the home visit, the interventionist first provides education to the client to increase their

knowledge and influence their beliefs about postpartum sleep and fatigue and infant sleep. Then the interventionist uses a worksheet to encourage the client to identify one or two goals for themselves or their infant to work on over the next week. The client then creates a list of actions they believe will help to achieve the goal(s) and the interventionist helps to personalize the intervention to the client's context and available resources and ensure the goal is realistic and achievable. The client is charged with enacting the plan and on a follow-up phone call, the interventionist re-visits the goals and actions with the client to evaluate whether the goal(s) was achieved. Options include advancing to new goals or to create a new plan of action if the goal(s) was not achieved, provided the goal is still a priority for the participant. The interventionist also has an option to complete two alternative worksheets with a client called "What to do after a bad night" and "What to do after a good night". These are used either when a plan of action is derailed by unforeseen circumstances such as the infant becoming sick or when an unusually good quality or quantity of sleep is obtained. These worksheets intend to help clients learn from the 'good' or 'bad' experience to promote better sleep and reduce fatigue.

Structurally, the HUGS intervention was designed to address sleep and fatigue in the early postpartum (e.g., 2–3 weeks after birth) when the experience of these phenomena are still in the acute phase so that the effects of chronic sleep deprivation and severe fatigue on physical and mental health outcomes are more likely to be mitigated by preventive efforts (Doering Runquist et al., 2009; Lawson et al., 2015). Similarly, the early postpartum period is when behavior patterns around the management of fatigue and sleep are re-negotiated due to the presence of the new infant (Doering & Durfor, 2010; Kennedy, Gardiner, Gay, & Lee, 2007). The HUGS intervention was designed to capitalize on this natural period of change in a postpartum woman's life when she may be more amenable to testing new patterns of behavior, due to the acute experiences of postpartum fatigue and sleep deprivation. Intervention components were designed to be delivered in an initial 1-hour face-to-face home visit facilitated by a client booklet. This booklet guided the interventionist and client through the intervention components in the initial home visit. In addition, the booklet was intended to be used by the client as 1) A reference for strategies to improve sleep (addressing knowledge and beliefs), 2) A workbook to enact the goal setting and action planning process (addressing self-regulation skills and abilities and social support), and 3) During follow-up phone calls to document evaluation of current goals and promote continued engagement in the self-management process.

While sleep and fatigue are conceptually and methodologically two distinct concepts, these concepts are frequently paired in both qualitative and quantitative studies (Doering & Durfor, 2010; Insana & Montgomery-Downs, 2010; Kennedy et al., 2007; Rychnovsky & Hunter, 2009). The interconnectedness is noted in literature where postpartum fatigue is frequently linked to one or more nights of poor sleep (Doering & Durfor, 2010; Kennedy et al., 2007; Runquist, 2007). Conversely, women describe fatigue easing as sleep improves over the months after childbirth. Further evidence of this pairing is noted implicitly and explicitly within interventions that aim to target either postpartum sleep or fatigue. For example, tips for managing sleep often also address fatigue; likewise, interventions to manage fatigue frequently provide advice for managing sleep (Giallo et al., 2014; Stremmler et al., 2013; Troy & Dalgas-Pelish, 2003). For these reasons, the HUGS intervention was

designed to target the co-occurring phenomena of postpartum fatigue and sleep both in intervention content and as primary outcomes.

METHOD

Design, Sample, and Setting

This feasibility pilot study used a quasi-experimental repeated measures design. Eligibility criteria included being at least age 18, Medicaid enrolled (a health insurance program for low-income individuals and those with disabilities), access to a personal phone and a healthy singleton newborn. Exclusion criteria included issues that knowingly affected fatigue and sleep such as diagnosed sleep disorders or mental illness, use of pain medications unrelated to the birth, substance use, shiftwork, and intimate partner violence. Exclusion criteria were chosen to minimize the confounding effects these issues are known to have on fatigue and sleep. The comparison condition was an attention controlled intervention designed to teach participants about healthy eating, the relationship between food and sleep, and safe infant sleep, but not to address any aspect of self-management.

Variables

The independent variable was the treatment group consisting of either the HUGS intervention or attention control intervention. Dependent variables were postpartum fatigue, subjective sleep, and objective sleep-wake patterns (including total sleep time and sleep maintenance). Feasibility was evaluated based upon whether the HUGS intervention could successfully be carried out and demonstrate beginning effects on the target variables of postpartum fatigue and sleep. Acceptability was evaluated through open-ended evaluation questions.

Procedure

After obtaining university institutional review board approval, potential participants were screened by a research assistant for eligibility during their inpatient postpartum stay at a Midwestern urban medical center in the United States where 84 percent of the approximately 2,500 women giving birth annually have Medicaid insurance. Thirty-seven of the 113 total screened potential participants were ineligible (Figure 1). The most common reasons for ineligibility were mental illness ($n = 19$) and not on Medicaid ($n = 10$). Contact information was obtained for 76 eligible interested participants. At week 2 postpartum, 33 of the 76 participants were reached by phone and visited in person to obtain consent and baseline measures. The 43 participants who were unable to be reached did not differ demographically from those who were reached. Once baseline data were obtained, participants were randomized to either the HUGS treatment or comparison groups. However, only the first 21 participants were randomized (11 to the experimental condition and 10 to the control condition), because several consecutive weeks of low census at the recruitment site created time constraints that required randomization be ended. Instead, priority was given to ensuring the primary aim of evaluating the HUGS intervention feasibility. As a result, remaining participants were assigned to the HUGS group until 15 participants were assigned. The last two participants were assigned to the comparison condition.

The first author, who was the study's principal investigator (PI), randomized participants to the HUGS or comparison intervention using a random number table and communicated participant assignment to the interventionist. After group assignment, the interventionist then conducted a home visit at week 3 postpartum to deliver the assigned intervention. Follow-up reinforcement phone calls were delivered 48 hours, 1, 2, and 3 weeks after the home visit, which corresponded to postpartum weeks 3, 4, 5, and 6 (Figure 2). The interventionist, an advanced practice nurse with expertise in mental health, was trained and monitored by the PI to ensure standardization of delivery. The PI evaluated the interventionist's delivery of the first two participants of each study condition to ensure no sleep, fatigue, or self-management content was provided to participants of the control condition. Fidelity checklists were maintained by the interventionist for all home visits and phone calls for both study conditions and checked by the PI. The interventionist had a long-standing trusting relationship and practice within the community and was of the same race (African-American) as the majority of the study sample. The interventionist delivered both study conditions so that the interventionist's rapport with participants was controlled; however the interventionist was not blinded to which condition was the intervention. Data were collected by the research assistant. The PI monitored progress of the study through an online tracking system. The research assistant and interventionist had no contact with each other and the research assistant remained blinded to the participants' assigned condition throughout the study. Post-treatment data collection occurred by home visit at postpartum weeks 4, 6, and 9, which corresponded to weeks 1, 3, and 6 after the initial intervention home visit. Participants received a total of \$100 plus nominal tokens over the study period.

Outcome Measures

Postpartum fatigue.—Postpartum fatigue was measured by the Modified Fatigue Symptoms Checklist (MFSC) (Pugh, 1993). This 30-item yes/no checklist measures postpartum fatigue intensity for physical and mental fatigue. Scores are summed and range from 0 to 30 with higher scores indicating higher fatigue levels. The MFSC is a valid and reliable tool that is commonly used in postpartum women, including in the study's geographic area (Doering Runquist et al., 2009; Milligan, Parks, Kitzman, & Lenz, 1997). Reliability in the current study was $\alpha = .90$.

Subjective sleep disturbance.—Sleep disturbance was measured with the Generalized Sleep Disturbance Scale (GSDS) (Lee, 1992). The GSDS is a valid and reliable measure of postpartum sleep disturbance in the past week. Responses to the 21 questions range from 0 to 7 days, scores are summed to create a total score that can range from 0 to 147 with higher scores indicating more sleep disturbance. Reliability in this study was $\alpha = .82$.

Sleep-wake patterns.—Objective sleep-wake patterns were measured by 72 hour wrist actigraphy (Basic Motionlogger®, Ambulatory Monitoring Inc.) at six weeks postpartum. The timing of actigraphy was selected to give participants time to begin to apply the intervention to their lives. Actigraphy data were collected during weekdays, and participants kept sleep diaries. Sleep diaries included bed and rise times, perceived awakenings, actigraph removal, daytime naps, use of bedroom TV, fan, disturbing noises, and bed-sharing

(Table 1). Selected outcome variables included total sleep time after sleep onset and sleep maintenance (i.e., percent of time spent asleep after sleep onset).

Intervention acceptability.—At week 9, participants in both treatment groups evaluated the interventions through one yes/no question, “Would you recommend this program to your friends,” and several open-ended responses including: “In this program, what was the most important thing we did?,” “What was the least helpful thing we did?,” “What information or ideas were missing from this program?,” and “What did you want more information about?”

Data Analysis

Descriptive statistics were calculated for participant characteristics and described levels of fatigue and sleep. Fixed effects regression was used to model each group’s trend over time while accounting for each subject’s baseline scores. The small sample size precluded controlling for parity, type of infant feeding, or manner of birth (operative or vaginal). Priority was given to evaluating the intervention’s feasibility in a diverse sample. Actigraphy data were analyzed using Action 4, Cole-Kripke 1-minute algorithm, and inputted into SPSS 17.0 with additional analysis performed with SAS 9.13. All raw data were double entered for quality control. Written responses to intervention evaluation were organized through thematic content analysis.

RESULTS

Participants

Of the 33 consented participants, 7 were not included in the analysis. Of the 7 excluded participants, 1 withdrew prior to the intervention, 5 could not be reached for intervention delivery, and 1 could not be reached for the post-intervention data collection resulting in complete data for 15 HUGS and 11 comparison participants. Chi square analysis revealed no differences between study groups on basic demographic variables (i.e., age, education, race/ethnicity, marital status, and income). Participants in both groups were primarily in their mid-20’s, never married, non-Hispanic, African-American, multiparous, had given birth vaginally, and were on Women, Infants, and Children (WIC) and food stamps. In the United States, WIC and food stamps are federal food assistance program for individuals and families. Most participants reported sleeping in a bed most nights, but 3 participants from each group reported their main sleeping space was a couch or floor. At least 80 percent in each group had a television in the bedroom, which was on at the time of sleep for an average of about 5 nights each week (Table 1).

Feasibility

Intervention components were delivered primarily in the home visit, which lasted on average 60 minutes for the HUGS intervention and 41 minutes for the comparison group (see Table 2). If any intervention components were unable to be delivered at the home visit, the interventionist tracked these components on the fidelity checklists, covered remaining components in subsequent phone calls, and reinforced previously delivered components to ensure a full intervention dose was delivered to all participants. While completing home visits was accomplished for all participants in both groups, reaching participants for the 4

follow-up phone calls was challenging and required, on average, 10 phone calls (HUGS) or 9 (comparison) by the interventionist to complete an average of 1.9 (HUGS) and 2.3 (comparison) follow-up calls per participant. Despite repeated attempts to reach participants, only 1 participant from each study condition completed all 4 follow-up phone calls. All participants except for one (lost to follow-up) were reached for data collection.

The primary outcome variables were postpartum fatigue (MFSC), sleep disturbance (GSDS), and sleep-wake patterns (total sleep time and sleep maintenance). The HUGS group had significantly worse fatigue ($p = .02$) and sleep disturbance ($p = .04$) at baseline (week 2), although there were no significant demographic differences found between groups. Over time, however, the HUGS group showed significant improvement relative to the comparison group, until week 9, when it exceeded the comparison group on both measures (Figure 3, Figure 4). Using fixed effects regression, the intervention by time interaction was significant for both fatigue ($p < .001$) and sleep disturbance ($p < .001$) with the HUGS group having a 1.15 point drop in fatigue per week compared to the control group and a 4.84 point drop in sleep disturbance compared to the comparison group. Table 3 shows the predicted mean scores and their confidence intervals; for both fatigue and sleep disturbance the HUGS group performed significantly better by the end of the study period.

Actigraphy data were available for only 22 of 33 participants (13 HUGS, 9 comparison) due to actigraph malfunctions or participants forgetting to wear the actigraph after removing for showers, baby baths, etc. No difference ($p = .71$) was found when the total sleep time for night 1 was compared to nights 2 and 3, so data across all 3 nights were averaged. No differences were found between study groups on total nocturnal sleep time [HUGS: $M = 318$ (80.5) minutes or 5.3 hours; Comparison: $M = 324$ (72.2) minutes or 5.4 hours] or sleep maintenance (see Table 4). Sleep environment data from sleep diaries revealed that: 1) Sleep was disturbed by nocturnal noises for 91 percent of the total sample ($n = 26$), that 2) Half of the sample slept with the TV on in the bedroom all night every night, and that 3) Most participants (72%) primarily slept in a bed, but that some participants slept on a couch (19%) or floor (6%) (Table 1).

Acceptability

Only HUGS intervention participants were asked to set goals as part of the self-management process. HUGS participants were actively engaged in goal setting during the study, and goals tended to reflect intervention content. For example, 41 goals were set by the 15 HUGS participants at the initial home-visit. Of these 41 goals, 9 themes related to the self-management of sleep and fatigue emerged. The most frequent goals recorded were: Developing a routine for baby ($n=9$); Worrying less/decreasing stress ($n=8$); Feeling less tired ($n=6$); Getting more sleep ($n=6$). Figure 5 shows an example of one HUGS participant's goal setting activity over the course of the study.

Participants in both groups were asked to evaluate the intervention experience at the end of the study. Nearly all ($n = 14$) HUGS participants and all ($n = 11$) attention control participants indicated they would recommend the intervention to friends or family. When asked 'what was the most important thing we did,' all participants in each group responded. The most frequent answer for HUGS participants was 'Help me set up goals for me and my

baby to sleep better' (5 of 15) and 'Help my baby get into a routine' (4 of 15). When asked what was the 'least helpful,' 10 of 15 participants said 'nothing.' Comparison group participants listed a variety of responses including 'Foods that can help you get more sleep,' and 'Making me think about my sleep and make me realize I don't get as much as sleep as I should.' When asked what participants wanted more information about, 11 of 15 HUGS participants and 4 of 11 comparison group participants said 'nothing' or 'you told me everything.' However, several comparison group participants desired more information including: 'How to put baby into a routine,' 'Reasons why you may not be able to sleep,' and 'How to be healthy'. When asked what could make the program better, HUGS participants requested the materials be in Spanish and to advertise 'to get as many moms as possible,' and 10 of 11 comparison group participants responded 'nothing.' Several multiparous participants told the study staff they wished they had intervention information with their previous pregnancies. Finally, the partners or other family members in about one-third of participants sat in on the home visit with the interventionist and were eager to know how they could participate in helping the mother sleep better and feel better.

Cost

Intervention cost was measured as the total nurse time spent delivering the interventions and making follow-up phone calls (travel time excluded) using the U.S. Bureau of Labor Statistics 2011 mean for hourly wage and benefits (\$47.47). The mean time spent delivering the comparison condition was 72 minutes at a cost of \$57 per participant. The HUGS intervention, on average, cost an additional 28 minutes of time for a total mean delivery cost of \$79.

Discussion

Results of this study support the feasibility and acceptability of the HUGS intervention to promote self-management of postpartum fatigue and sleep. The study protocol was successful in carrying out the data collection protocol for measures including 0 (baseline), 1, 3, and 6 weeks post-treatment. The feasibility and fidelity data obtained provided solid evidence for improving the intervention content and structure for future studies. Despite the HUGS group's baseline sleep and fatigue levels being higher than the control group's and given the interventionist was only able to reach approximately half of participants for follow-up phone calls, the HUGS group's fatigue and sleep improved over the comparison group, perhaps indicating the home visit provided an effective intervention dose. Given the challenges with reaching participants by phone and the fact that several participants completed study content by phone when interruptions prevented the full intervention being delivered, a second nurse home visit within 1 week after the first home visit is recommended in future studies, although the optimal timing of this visit may be evaluated in future studies.

While no differences between study groups were found on sleep-wake patterns, the finding that women in both groups were getting approximately 5.3 hours per night over a three night period at six weeks postpartum was far less than the 7.2 hour average reported in the literature (Montgomery-Downs et al., 2010). This alarmingly low quantity of sleep at 6 weeks postpartum is below the 10th percentile of the normed reference cited in

Montgomery-Downs et al. This has serious implications for compromised health and functioning of this population, especially in relation to mental health, since there is evidence of the relationship between sleep and mood in postpartum women (Coo et al., 2014). The poor quantity of sleep found in this sample is congruent with other findings that sleep is compromised in populations living in socioeconomic disadvantage and warrants urgent further investigation (Mezick et al., 2008; Moore et al., 2002).

Participant sleep disturbance as measured by the Generalized Sleep Disturbance Scale (GSDS) was higher in the HUGS and control groups than the level reported by Lee and Gay (2011). The lower income sample (i.e., sample 2, $n = 122$) in Lee and Gay's study reported a mean GSDS score of 50 (± 15 intervention group, ± 19 control group) at 1 month postpartum with a score of 43 or higher indicating poor sleep. In the current HUGS study the mean GSDS score at 1 month was 69 (± 11) in the intervention group and 55 (± 20) in the control group. Lee and Gay's sample included 12% African-Americans while the HUGS study included 73% (HUGS) and 67% (control) African-Americans. These findings also suggest the need for further investigation of subjective sleep in postpartum African-American women, especially given the relationship between subjective sleep and postpartum depression (Goyal, Gay, & Lee, 2007; Rychnovsky & Hunter, 2009).

Participant levels of postpartum fatigue followed a similar pattern. A score of 6 or higher on the Modified Fatigue Symptoms Checklist (MFSC) indicates severe fatigue (Corwin, Brownstead, Barton, Heckard, & Morin, 2005). Although the control group had lower fatigue (ranging from a mean of 5.6 to 6.2) than the intervention group, the control group's fatigue did not improve from postpartum weeks 2 to 9. The intervention group's mean fatigue level ranged from 7.6 to 13.1 and even though the intervention group's fatigue improved over the study period, the group on a whole reported severe fatigue over the entire study period. These fatigue levels are similar to those found in a similar sample (i.e., urban, 75% African-American) of 43 postpartum women who reported a mean MFSC score of 11.4 at 1 month postpartum (Doering Runquist et al., 2009). Again, the importance of addressing fatigue to improve postpartum health is emphasized by the finding that severe fatigue and depressive symptoms commonly co-occur and that severe fatigue may in some cases, predict depressive symptoms (Corwin et al., 2005; Doering Runquist et al., 2009).

The IFSMT, which promotes the idea of "family self-management" aligns well with the intervention delivery experience in this study. While the HUGS intervention was focused on the individual postpartum woman, the experience of carrying out the intervention in this study resulted in several instances of family member participation in support of the participant achieving her goals to manage sleep and fatigue. We recommend that future studies of this intervention include the flexibility to involve family member participation in the self-management plan when appropriate to the family's context. For example, this could include a page in the intervention booklet for mothers to outline what actions family members (and even older children in some cases) can do to help the mother. This page can be posted on the refrigerator and discussed at follow-up. Furthermore, as mothers engage in behaviors such as routine setting around bedtime for themselves, such self-management behaviors also have the potential to improve the sleep of other family members, which is an area for expansion of this intervention beyond the postpartum period.

This is the first known published study that evaluates intervention cost within the area of postpartum sleep and fatigue. Future study designs can extend the evaluation of cost to include cost-benefit and cost-effectiveness analyses to contribute to building the science of comparative effectiveness interventions and advance the translation of effective interventions into practice more efficiently (Grosse et al., 2007).

Limitations

We acknowledge several limitations. Subjective sleep appeared to be more modifiable by the intervention than objectively measured sleep-wake patterns, however, equipment challenges prevented complete data from being collected. In addition, to reduce participant burden, actigraphy data were collected only once and perhaps too close to the intervention, thereby not allowing enough time to lapse to see self-management behaviors affect objective sleep-wake patterns. Additional measures of study outcomes beyond 9 weeks postpartum are recommended in future studies to assess the sustainability of the intervention effectiveness on health outcomes. Future efficacy studies should control for possible confounding variables such as type of infant feeding, type of birth (operative or vaginal) and parity.

Several challenges with recruitment and retention were limitations on this study. The greatest challenge with recruitment and retention was reaching those mothers who qualified for the study inpatient, but who could not be reached to schedule a week two visit to obtain consent and baseline data. The most common reason for being unable to contact eligible potential participants was either changed phone numbers or no return contact after leaving multiple messages. Difficulty reaching participants by phone for follow-up intervention visits was another challenge. On the other hand, while only five of the HUGS participants were able to be reached for the last follow-up phone call by the interventionist, all HUGS participants completed data collection, which had a monetary incentive associated with completion. Future recommendations include incentivizing both intervention delivery and data collection. Furthermore, providing participants with disposable cell phones for study use may improve follow-up.

Conclusion

Helping U Get Sleep (HUGS) is a promising new theory-guided intervention delivered in the early postpartum period that aims to reduce postpartum fatigue and promote postpartum sleep through self-management in socioeconomically disadvantaged women. Future recommendations are to modify the intervention based upon the available data, test the efficacy of the modified intervention in a larger sample, translate the intervention into Spanish, apply the intervention to broader postpartum populations, and adapt the intervention to mHealth platforms. The intervention's self-management approach of augmenting traditional knowledge-based interventions with such components as goal setting, action planning, decision-making, self-monitoring and social facilitation also holds potential for expansion to populations beyond postpartum women who struggle with problems related to poor sleep and fatigue and their associated health consequences.

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Figure 1.
CONSORT diagram of participant flow.

Postpartum Week	0	2	3	4	5	6	9
	Eligibility screen	Consent					
Intervention			Home Visit + call 48 ^o after	Call	Call	Call	
Data collection		X		X		X [*]	X

*72 hour actigraphy

Figure 2.

Intervention delivery and data collection protocol timeline; identical for both conditions.

HUGS condition ($n = 15$); Comparison condition ($n = 11$).

Figure 3.

Changes in postpartum fatigue by study condition denoted by mean and standard deviation.

HUGS condition ($n = 15$); Comparison condition ($n = 11$).

Figure 4.

Changes in sleep disturbance by study condition denoted by mean and standard deviation.

Figure 5.
Example of goal setting by one HUGS participant across the study period.

Table 1.

Demographics, sleep environment characteristics, and health status by study condition at baseline.

	HUGS (<i>n</i> = 15) <i>Mean (SD) range or n (%)</i>	Comparison (<i>n</i> = 12) <i>Mean (SD) range or n (%)</i>
Age	25.13(5.28), 18–35	26.0(4.24), 18–32
Years of education completed	11.7(1.05), 9–13	12.7(2.02), 10–16
Marital Status		
Never married	11 (73)	9 (75)
Married	2 (13)	-
Member of unmarried couple	2 (13)	1 (8)
Separated	-	1 (8)
Divorced	-	1 (8)
Ethnicity		
Hispanic/Latino	2 (13)	2 (25)
Non-Hispanic/Latino	11 (73)	11 (67)
Missing	-	1 (8)
Race		
Black or African-American	11 (73)	8 (67)
White or Caucasian	2 (13)	1 (8)
Missing	2 (13)	3 (25)
Annual household income		
\$0 to \$4,999	4 (27)	2 (17)
\$5,000 to \$14,999	3 (20)	3 (25)
\$15,000 to \$34,999	2 (13)	3 (25)
\$35,000	-	1 (8)
Not sure/Don't know	6 (40)	3 (25)
Type of birth		
Cesarean Section	1 (7)	3 (25)
Vaginal	14 (93)	9 (75)
Infant feeding method		
Formula	7 (47)	6 (50)
Breast milk	5 (33)	1 (8)
Formula and breast milk	3 (20)	5 (42)
Times given birth	2.9 (1.55), 1–7	2.8 (1.29), 1–5
Primiparous	2 (13)	3 (25)
Multiparous	13 (87)	9 (75)
WIC (Women, Infants and Children)		
Yes	15 (100%)	10 (83)
No	-	2 (17)
Food Stamps		
Yes	14 (93)	9 (75)
No	1 (7)	3 (25)

	HUGS (<i>n</i> = 15) <i>Mean (SD) range or n (%)</i>	Comparison (<i>n</i> = 12) <i>Mean (SD) range or n (%)</i>
Sleep location most nights		
Bed	12 (80)	8 (67)
Couch	2 (13)	2 (17)
Floor	1 (7)	1 (8)
Other	-	1 (8)
TV in bedroom	12 (80)	10 (83)
No TV in bedroom	3 (20)	2 (17)
TV on at sleep onset:		
All the night	4 (27)	1 (8)
Part of the night	5 (33)	5 (42)
I never go to sleep with the TV on	5 (33)	4 (33)
Sleep with a fan on:		
All the night	2 (13)	3 (25)
Part of the night	1 (7)	1 (8)
I never go to sleep with a fan on	12 (80)	8 (67)
Sounds or noises at night wake you		
Yes	13 (87)	12 (100)
No	2 (13)	-
Overall my health is:		
Excellent	2 (13)	2 (17)
Good	8 (53)	8 (67)
Fair	8 (53)	2 (17)
Poor	-	-

Table 2.

Feasibility data delineated by study condition.

	HUGS (<i>n</i> = 15) <i>M(SD)</i>	Comparison (<i>n</i> = 12) <i>M(SD)</i>
Time to deliver intervention at home visit	60 (19.0) minutes	41 (12.7) minutes
Time spent delivering intervention by phone	25 (12.2) minutes	22 (18.1) minutes
Total minutes to deliver intervention (home visit + phone calls)	85 (25.0) minutes	63 (26.3) minutes
Number follow-up phone calls completed (4 possible)	1.9 (0.96)	2.3 (0.99)
Number of attempts by interventionist to reach participants by phone over study protocol	10 (4.2)	9 (2.0)

Table 3.

Predicted mean scores with 95 percent confidence intervals for postpartum fatigue (MFSC) and sleep disturbance (GSDS), from fixed effects regression with a linear time component.

Weeks	Postpartum Fatigue (MFSC)		Sleep Disturbance (GSDS)	
	HUGS** M(CI)	Comparison** M(CI)	HUGS** M(CI)	Comparison** M(CI)
2*	12.49 (9.89,15.00)	9.16 (7.97,10.35)	69.80 (58.55,81.04)	60.33 (54.66,65.70)
4	10.31 (8.53,12.11)	9.29 (8.19,10.39)	59.33 (51.29,67.36)	59.54 (54.61,64.47)
6	8.15 (6.74,9.55)	9.41 (7.94,10.89)	48.86 (42.54,55.17)	58.75 (52.13,65.37)
9	4.89 (2.99,6.78)	9.60 (7.18,12.02)	33.15 (24.65,41.66)	57.56 (46.70,68.42)

* Baseline

** HUGS condition ($n = 15$); Comparison condition ($n = 11$)

Table 4.

Sleep-wake patterns as measured by 72 hour wrist actigraphy at week 6 postpartum.

	HUGS (<i>n</i> = 13)* <i>M(SD)</i>, range	Comparison (<i>n</i> = 9)* <i>M(SD)</i>, range
Total sleep Time (minutes)	318 (80.5), 159–502	324 (72.2), 244–268
Sleep Maintenance (percent)	74.5 (11.76), 56.5–97.7	69.6 (12.88), 52.4–85.4

* Missing data due to actigraph malfunctions and forgetting to put actigraph on after temporary removal