Improving Sleep Hygiene Behavior in Adults Living with HIV/AIDS: A Randomized Control Pilot Study of the SystemCHANGE™-HIV Intervention

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Introduction

Insomnia and fatigue are among the earliest and most distressing complaints of people living with HIV, (K. Lee, C. Portillo, &, & H. Miramontes, 2001; Reid & Dwyer, 2005; Salahuddin, Barroso, Leserman, Harmon, & Pence; Vosvick, et al., 2004) who are more likely to experience insomnia symptoms than uninfected adults (Jean-Louis G, 2012). A systematic review found that 74% of people living with HIV have insomnia and that these disturbances occur at all stages of HIV disease. Increased sleep disturbances put them at

increased risk for all-cause mortality.(Alvarez & Ayas, 2004; Patel, et al., 2004; Reid & Dwyer, 2005) Sleep is a complex biopsychosocial process several unique factors have been found to mediate and/or moderate sleep in people with HIV including medical variables including type of HIV medication, time since HIV diagnosis, HIV viral load, presence of other diseases (infections, depression); environmental and social variables including living conditions (noise, safety, private space) and social support; and personal characteristics such as employment status, illicit drug use, perceived stress, sleep habits, and history of incarceration.(K. A. Lee, C. J. Portillo, & H. Miramontes, 2001; Nokes, 2001; Phillips & Branson, 2009; Reid & Dwyer, 2005; Saberi, Neilands, & Johnson, In press) Among those living with HIV, poor sleep quality has been found to lead to negative health outcomes, HIV medication nonadherence, and diminished quality of life.(McDaniel, Buboltz, Chauvin, & Eddlemon, 2011; Reid & Dwyer, 2005; Saberi, et al., In press) Consequently, interventions to improve sleep may have a significant positive impact on health outcomes for people living with HIV.

Most interventions to improve sleep involve medical management strategies such as central positive airway pressure for sleep apnea,(Issa & Sullivan, 1986; Naughton, Liu, Bernard, Goldstein, & Bradley, 1995) prescribed and over-the-counter medications,(Morin, et al., 2009; NIH, 2005) and light therapy for other sleep problems.(Wilson, et al., 2010) These methods can be cumbersome and may have adverse effects. Behavioral interventions may also improve sleep but in a less burdensome and more efficient way. People living with HIV have unique barriers to proper sleep hygiene which are often overlooked in traditional medical management of sleep disturbances. Lee and colleagues (2012) found that, contrary to the accepted sleep paradigm, traditional risk factors for poor sleep (high BMI, anthropomorphic factors) were not associated with sleep disorders in people living with HIV.(K. Lee, et al., 2012) They conclude that targeted behavioral interventions focusing on sleep hygiene and environmental factors may be more effective than traditional medical interventions focusing on body weight to improve sleep in this population. This finding has been supported by research in other populations. (Haesler, 2004; K. A. Lee & Gay, 2011)

Previous research involving people living with HIV has found that sleep disturbances are among the most troubling aspects of HIV self-management, with 35% of subjects desiring interventions to improve sleep quantity and quality.(Webel, 2012) Nonetheless, few studies have examined how to improve healthy sleep in this group, particularly through behavioral sleep hygiene interventions. (Phillips & Branson, 2009; Reid & Dwyer, 2005) Limited research has been done in sleep behavior interventions. Dreher (2003) found that decreasing caffeine consumption led to increased sleep quality in those with HIV. (Dreher, 2003) Phillips and Skelton (2001) found that twice-weekly acupuncture improved subjective sleep quality in a one-group experimental study of 21 people living with HIV. (Phillips KD, 2001) Most recently, Hudson, et al.(2008) found that an individually tailored sleep hygiene intervention increased nighttime sleep in 30 women with HIV.(Hudson, Portillo, & Lee, 2008) Although promising, this work lacks a control group, has not been replicated or expanded to other HIV/AIDS populations and does not examine the sustained effect of the intervention beyond 1 week. These limitations were addressed in our pilot study examining the feasibility of the SystemCHANGETM-HIV intervention.

The objective of this investigation was to evaluate the feasibility and estimate the magnitude of the effect of a novel, evidence-based behavioral intervention, SystemCHANGE™-HIV on sleep outcomes and quality of life in people living with HIV compared with a usual care control group. We hypothesized that the SystemCHANGE™-HIV intervention would be a feasible intervention for HIV+ adults, as indicated by ratings of perceived usefulness, applicability, and sustainability and that participants in the intervention would have increased sleep quality, sleep quantity, and increased quality of life.

Methods

Participants

This study was approved by the Institutional Review Board at University Hospitals, Case Medical Center. Participants included 43 HIV+ adults in Northeast Ohio. Our sample size was pre-specified to be 20 participants per group. This follows the methodology of Hertzog (2008) which showed that samples of 10–40 participants per group are adequate for evaluating feasibility in a pilot study.(Hertzog, 2008) We anticipated approximately 10% attrition and recruited 45 participants, of whom 43 attended the first study appointment and were enrolled. Inclusion criteria were: >18 years of age, speaking fluent English, and having a confirmed HIV diagnosis. There were no additional exclusion criteria. Sample participants were recruited through Infectious Disease clinics, AIDS Service Organizations, and through an approved HIV research registry via flyers, letters, and physician referral. All participants provided informed consent.

Procedure

All interested participants called a screening line to ensure that they met the inclusion criteria between November 2010 and January 2011. Those meeting inclusion criteria were scheduled to attend an initial appointment with a research assistant. At this initial appointment, participants completed an informed consent document and received instructions on how to use an actigraph and sleep diary for the next seven days. An actigraph device is worn on the wrist and contains an accelerometer that detects movement from which sleep/wake state can be determined using an algorithm that has been validated against EEG measures of sleep and wake time.(T. Blackwell, 2005) Upon correct demonstration of each tool the participants were sent home the actigraph device to wear and the diary to complete. At the end of one week, the participants returned with the actigraphs, completed sleep diaries, and completed a pen and paper survey (described below). Following these baseline assessments, participants were randomized to either a behavior intervention or a standard treatment control group using block randomization with randomly chosen block sizes of 2 and 4. A flow chart of study procedures is provided in Figure 1. Participants were paid $50 for completion of their assessments (per assessment). Those randomized to the intervention group immediately began the first intervention session and those randomized to the control group received a copy of the HIV Symptom Management Strategies: A Manual for People Living with HIV/AIDS. The participants in the control group were orientated on how to use the manual by a research assistant, and then were instructed to return in 10 weeks. (Wantland, et al., 2008) The intervention group was reminded to come to each session by a weekly phone call from the study staff. After 10 weeks both groups were called and reminded to come to the follow up assessment. All study visits occurred at a convenient community-based setting and all study procedures occurred between February and June 2011. This study was registered at clinicaltrials.gov with the trial registration number NCT01256814.

SystemCHANGE™-HIV Intervention

Those randomized to the intervention group were invited to return for 10 weekly sessions on different topics of HIV management, including sleep hygiene, and behavioral modification strategies. SystemCHANGE™-HIV is based on the successful SystemCHANGE™ intervention, grounded in a socioecologoical model. It represents a paradigm shift in behavioral interventions, by focusing on re-designing the system of the interpersonal environment and the daily routines linked to health behavior, rather than focusing on personal effort to change individual behaviors. (M. S. Alemi F, Baghi H., 2008; N. D. Alemi F, Ardito S, Headrick L, Moore S, Hekelman F, Norman L., 2000; Humpel, Owen, & Leslie, 2002) This approach was designed to assist individuals and their families to focus on

changing the daily systems in their lives (routines, events, circumstances) that affect health behaviors. SystemCHANGE™ has been previously validated in numerous populations and its theoretical basis has been described elsewhere.(Moore, et al., 2006; Moore SM, 2002) Each of the 10 group sessions were taught by either a trained Health Educator or a Registered Nurse. These facilitators used a semi-scripted lesson plan to increase the fidelity of information delivered. These lessons were based on SystemCHANGE™ theory and therefore encouraged environmental and not cognitive changes to improve health-related behavior changes in the participants. The crux of SystemCHANGE™ approach is to use small environmental changes to make significant improvements in health. This was done each week by encouraging participants to attempt weekly small tests of change and to modify those changes to be the most beneficial in self-managing their HIV, focusing on sleep. Both fidelity of receipt of the intervention (dose) and perceived effectiveness and applicability of each intervention session were assessed at the end of each session with a participant feedback form. Participants in the intervention group received a $10 gift card at the end of each session were given a bus pass or parking pass to compensate them for time and travel expenses.

Measures

Sociodemographics and health history were assessed with a brief demographic survey and medical chart abstraction form. This instrument consisted of 26 items about demographics and illness characteristics. It included questions on age, gender, race, ethnicity, education, income level, and health insurance. Additionally, participants consented to allow the research team to abstract the data from their medical chart.

Feasibility of Intervention was assessed using a written qualitative assessment at the conclusion of the intervention. The purpose of this instrument is to examine the feasibility of this pilot intervention. Our operational definition of feasibility came from Grady, Cummings and Hulley (2007). Accordingly, we captured data on the following: perceived usefulness, applicability to the population, and sustainability; as well as time required and cost of recruitment, qualitative assessment of willingness to accept randomization in future interventions and comply with intervention procedures; acceptance of measurement procedures, problems with completion, and time to complete instruments (Grady, 2007).

Sleep duration and quality were measured using wrist actigraphy (Actiwatch Spectrum, Respironics, Inc.). Subjects were taught proper use of the actigraph and were asked to wear the device continuously for 1 week at baseline, and again for 1 week at 10 weeks later. Bedtime intervals were manually set in a standardized fashion by a technician who was blinded to treatment assignment and then quantitative sleep measures were obtained using a validated sleep scoring algorithm.(Kushida, et al., 2001)

Our primary measures of sleep quantity were mean sleep duration and of sleep quality, the sleep fragmentation index and sleep efficiency. All three are widely used and validated measures of sleep duration and quality.(Lauderdale, et al., 2006; Montgomery-Downs, Insana, Clegg-Kraynok, & Mancini, 2010) Mean sleep duration was defined as the average over 1 week of the total amount of sleep obtained in the main sleep period as defined by the subject. The sleep fragmentation index measured the degree to which sleep is fragmented by periods of wake. (McLean, et al., 2005; van den Berg, et al., 2008) Sleep efficiency is a measure of the proportion of time actually spent asleep between sleep onset and waking. Both sleep efficiency and sleep fragmentation index were calculated for the main sleep period of each 24-hour interval and then averaged for the week of recording.

Sleep disturbances and sleep-related impairments were assessed using the validated Patient Reported Outcomes Measurement Information System (PROMIS) Sleep Disturbance and

Sleep-Related Impairments Scales.(Buysse, 2010) These scales measure self-reported sleep disturbances (trouble falling or staying asleep) and sleep-related daytime impairments (difficulty functioning due to poor sleep) in the past 7 days, and are normalized on a T distribution with a mean of 50 and standard deviation of 10. The Cronbach's alphas at baseline were 0.90 and 0.92, respectively, indicating good reliability of the scales.

Quality of life was measured using the HIV/AIDS Targeted Quality of Life Instrument. This widely-used, 34-item instrument is a disease-specific measure assessing nine dimensions: Overall function, life satisfaction, health worries, financial worries, medication worries, HIV mastery, disclosure worries, provider trust, and sexual function(Sousa, 1999). Each dimension was scored and reported individually. Reliability coefficients ranged from 0.83 to 0.88 for all dimensions. (Holzemer W., 2000) For this study a select subset of the dimensions, requiring only 10 of the 34 items, was used to indicate quality of life (overall function and life satisfaction subscales). The Cronbach's alphas at baseline 0.80 on the overall function subscale and 0.91 on the life satisfaction subscale.

Statistical Analyses

Descriptive statistics were used to summarize participant's demographic and clinical characteristics. For continuous variables we reported means and standard deviations, and categorical variables were reported as frequencies with percentages. All analyses maintained subjects in the original treatment groups (intent to treat). The treatment effect (intervention group minus control group) on each endpoint was estimated using ANCOVA models looking at the difference between baseline and end-of-study responses. Unadjusted analyses included only the baseline value of the endpoint and the treatment assignment as covariates. Adjusted analyses included age, sex, and years since HIV diagnosis as additional covariates. These additional covariates were chosen a priori as they have been shown to impact sleep quality and quantity. (Dreher, 2003; Ohayon, Carskadon, Guilleminault, & Vitiello, 2004; Reid & Dwyer, 2005)

Results

We conducted a two-group randomized control study with repeated assessments at baseline and end-of treatment (week 10) with 43 HIV+ adults, of whom 40 completed all study procedures (7% attrition). Our sample was predominately male (58%), African-American (8%), single (79%), and unemployed (91%). Medically, most had health insurance (86%), on average, had been living with HIV for 13 years, most were taking HIV anti-retroviral medications (95%), and most had an undetectable HIV viral load (67%). Four percent of our sample had been diagnosed with sleep apnea (n=2; one participant in the intervention group and one participant in the control group). There were no statistically significant differences in baseline characteristics between participants in the intervention group and those in the control group. For more details on the demographic and medical characteristics, see Table 1.

Mean sleep duration and sleep efficiency for the members of the control group vs. the SystemCHANGE™-HIV intervention group (5.5 +/−2.1 hrs vs. 6.5+/−1.6 hrs; and 78.0 % +/−13.1 vs. 82.0% +/− 8.7) tended to be lower, but not statistically significant, at baseline. Conversely, sleep fragmentation (33.9 % +/− 14.9 vs. 28.8% +/− 11.7), self-reported sleep disturbances (59.0 +/− 9.5 vs. 57.8 +/− 6.7), and self-reported sleep related impairments (55.8 +/− 8.1 vs. 53.0 +/−9.1) in members of the control group vs. the SystemCHANGE™-HIV intervention group tended to be greater, but not statistically significant, at baseline (Table 2).

On average, SystemCHANGE™-HIV intervention participants attended 71% of all sessions (74% per protocol), rated the intervention as highly useful (77% rated it as superior or

excellent), worth their time (76% rated it as superior or excellent), and all thought it would be useful in the future (94% rated it as superior). Overall intervention satisfaction ratings were high, with 44% rating it as a superior program, 25% as excellent, and 31% as a good program. Ninety-three percent of participants reported using the information that was taught during the 10-week program, and 86% applied the intervention content to other habits, including smoking cessation and searching for employment. The cost of the intervention was $187 per participant. When asked what they would pay for the intervention, the mean amount if the participant was self-paying was $177 (+/− $222) and the mean amount if insurance was paying was $479 (+/− $386). Participants also provided a number of brief qualitative comments expressing their level of interest in the SystemCHANGE™-HIV intervention and perceived effectiveness of the intervention Representative quotes from these comments, as well as additional intervention feasibility data, are presented in Table 3.

At the end of the intervention, participants in the SystemCHANGE™-HIV intervention experienced a 10 minute/night increase in sleep time (t=0.38, p=0.71), a 2.3% absolute increase in sleep efficiency (t=0.98, p=0.33), a 2.0% absolute decrease in sleep fragmentation (t=−0.58, p=0.57), a 0.7%-point decrease in sleep disturbances (t=−0.27, p=0.79), and a 0.5%-point increase in sleep-related impairments (t=0.16, p=0.88) relative to the control group, based on the model estimates of the treatment effect adjusted for age, sex, and years since HIV diagnosis. Additionally, participants in the intervention group experienced a 2.1 point increase in life satisfaction (t=0.28, p=0.79) and 3.0 point increase in overall functioning (t=0.58, p=0.57) relative to control group based on the model estimates of the treatment effect adjusted for age, sex, and years since HIV diagnosis. Additional outcome statistics are reported in Table 4.

Discussion

This is the first study of the SystemCHANGE™ approach to behavioral change in adults living with HIV. The findings from our pilot study suggest that the SystemCHANGE™-HIV intervention is a feasible behavioral intervention to improve sleep and quality of life in adults living with HIV. Using an intent-to-treat analysis, we found that participants attended, on average, 71% of all intervention sessions (74% per protocol). This high attendance rate supports the feasibility of the experimental intervention.(Atkins CJ, 1990) We found that participants believed the intervention was useful, both in the present and in the future; they perceived it has wide applicability to important behavioral outcomes; and that it was a program worth investing time and money in. As sleep has become recognized as an important factor in maintaining and improving health outcomes in disease conditions (Alvarez & Ayas, 2004; Durmer & Dinges, 2005), and especially in HIV (Reid & Dwyer, 2005), there has been a corresponding increase in behavioral interventions targeting sleep in this population (Dreher, 2003; Hudson, et al., 2008; Naughton, et al., 1995; Phillips & Branson, 2009; Phillips KD, 2001). Recent scholarship has highlighted the importance of focusing behavioral interventions on environmental and sleep hygiene factors, rather than traditional physical factors in people living with HIV(K. Lee, et al., 2012). As SystemCHANGE™ has its theoretical basis in the socioecological theory and emphasizes personal system improvement; it is uniquely situated to address these issues. Furthermore, it is a paradigm that has successfully improved behavior change in other populations and our data suggest that with further refinement and study, it could also be successful among people living with HIV.

Although the results were not statistically significant due to our small sample size, they suggest that a refined SystemCHANGE™-HIV intervention may improve objectively-measured sleep outcomes. An increase of 10 minutes per night is an improvement over a previous sleep hygiene intervention in our target population. Hudson, et al. (2008) reported

no improvement in total sleep time for women living with HIV who underwent a tailored sleep improvement intervention.(Hudson, et al., 2008) We found improvement in both sleep efficiency (2.3%-point increase) and sleep fragmentation (2.0%-point decrease). Our evidence describing the effect of the intervention on self-reported sleep disturbances and impairments was mixed. While self-reported sleep disturbances decreased in the intervention compared to the control group, self-reported sleep-related impairments increased in the intervention group. This may be a function of the new PROMIS measures. Previously, these scales were rigorously validated in a large national study,(Buysse, 2010) but they have not been fully validated in a sample of HIV+ adults. This may have decreased the sensitivity of these measures to detect changes in perceived sleep quality. Future research should explore both questions in a larger sample of HIV+ adults.

An important part of feasibility of an intervention is whether it is sustainable. Accordingly, we tracked the cost of the intervention's implementation in order to determine whether the SystemCHANGE™-HIV intervention could efficiently be delivered to its target population. We found a total cost of delivering the 10 week intervention to 20 people was $3,731 or $185.65 per participant, which is consistent with other group-based self-management programs in the United States (Gordon C, 2007). Most of our costs were associated with the $10 incentive given to each participant for each session attended ($2,000) - a cost that could be minimized if adapted to a community-based setting which do not customarily give incentives for programs. Whether or not the SystemCHANGE™-HIV intervention could be deemed cost-effective, will be dependent upon whether a refined intervention is effective in future research. However, participants of the intervention reported that they would be willing to pay, on average $177 (+/− $222) for the 10 week intervention. If insurance was paying for the intervention, the perceived average value of the 10 week intervention increased to $479 (+/− 386). This discrepancy between the value of the intervention based on who was paying was not surprising. The actual cost of implementing the intervention was close to the average value if participants were self-paying (+ $9) and was well below the average reported value if insurance was paying (-$293). Taken together, the SystemCHANGE™-HIV appears to be a sustainable intervention which enhances the feasibility of the intervention.

While the results of this pilot study suggest that the SystemCHANGE™-HIV intervention is a feasible, and possibly effective intervention, our study has several limitations. First, our control condition was not a time-matched, attention-matched control condition. Those randomized to the control group received an effective HIV self-management manual and were oriented to how to appropriately use the manual, but did not attend weekly group sessions (as the intervention group did). Second, recruiting from multiple sites may allow for more generalizable findings. Third, our sample size (while appropriate for a pilot study) was too small to conclusively determine the efficacy of the intervention. It is possible that the apparent efficacy is an artifact of random chance and small sample size, but the direction and size of the results are consistent with a benefit that is worth pursuing in this at-risk population.

Notwithstanding these limitations, our pilot study provides preliminary data that support the possibility that a refined SystemCHANGE™-HIV intervention may efficiently improve sleep and quality of life in adults living with HIV—outcomes greatly desired by this population. Our data suggest that a larger randomized control trial of a refined intervention, with an appropriate time-matched attention control condition, in a larger sample of HIV-infected adults, examining the efficacy of the intervention is warranted.

Acknowledgments

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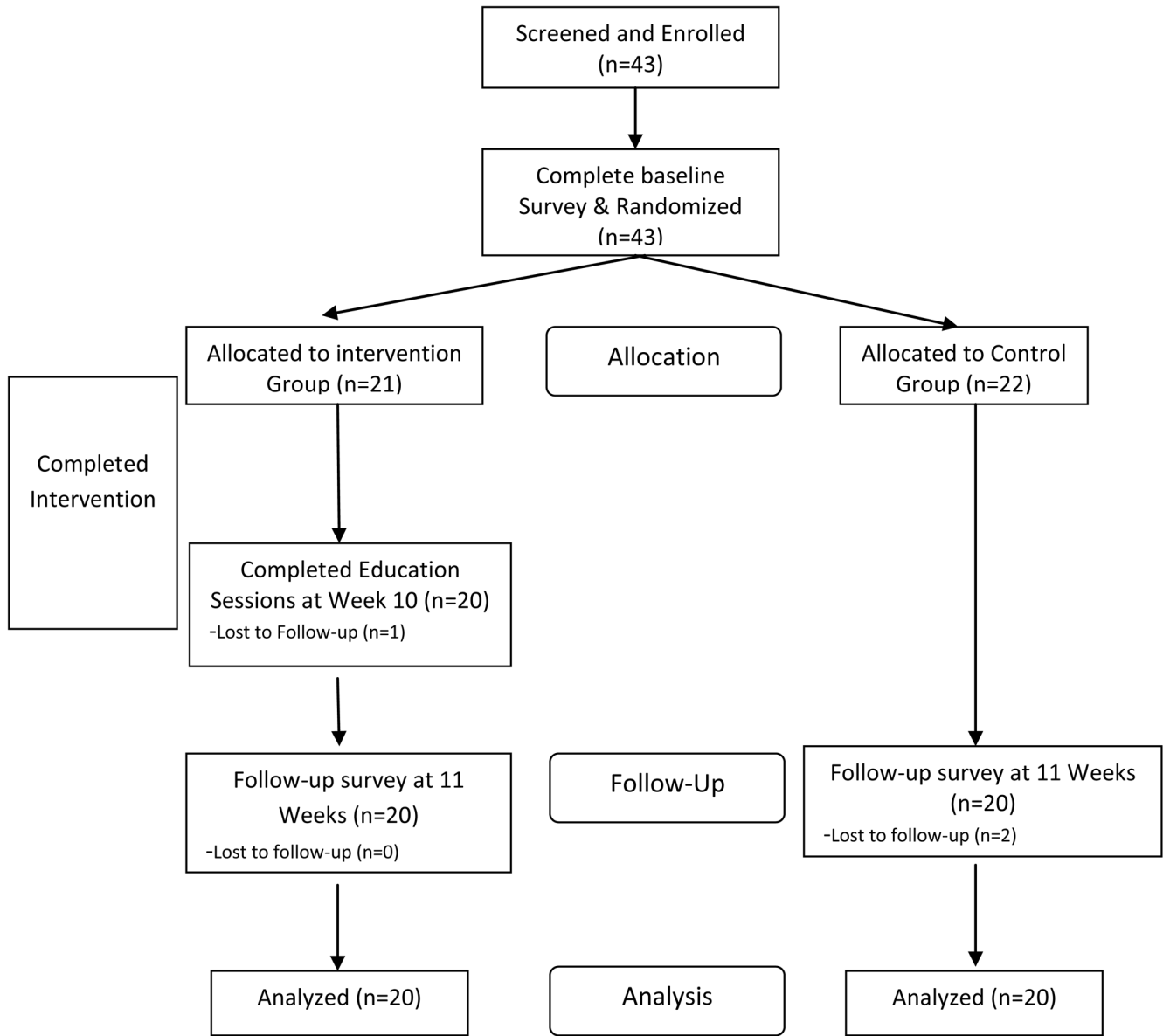
Figure 1.
Flowchart of SystemCHANGE -HIV Participants

Table 1

Demographic and Medical Characteristics of Study Participants

	Control Group (n=22)	Intervention Group (n=21)
	Frequency (%)[a]	Frequency (%)[a]
Mean Age (+/−SD), years	47.8 (6.4)	49.1 (7.4)
Female	9 (40.9)	9 (42.9)
Have Children	11 (50.0)	11 (52.3)
Number of children living with participant		
0	5 (22.7)	5 (23.8)
1	4 (18.2)	1 (4.8)
2	1 (4.5)	3 (14.3)
Race		
African American	18 (90.0)[b]	18(85.7)
White/Angelo	2 (10.0)[b]	2 (9.5)
Other	0	1 (4.8)
Marital Status		
Single	17 (77.3)	17 (81.0)
Divorced	4 (18.2)	2 (9.5)
Other	1 (4.5)	2 (9.5)
Education Level		
11th grade or less	7 (31.8)	6 (28.6)
High School or higher	15 (68.2)	15 (71.4)
Annual Income		
No monthly income	5 (22.7)	3 (14.3)
$1–$599	6 (27.3)	4 (19.1)
$600–$999	9 (40.9)	13 (61.9)
$1000 or more	2 (9.1)	1 (4.8)
Currently Works for Pay	3 (13.6)[c]	1 (4.8)
Has Permanent Housing	17 (77.3)[d]	21 (100)
Has Health Insurance	17 (77.3)	20 (95.2)
Type of Health Insurance		
Medicaid	9 (40.9)	11 (52.4)
Medicare	2 (9.1)	3 (14.3)
Private, not by work	3 (13.6)	2 (9.5)
Other	1 (4.5)	1 (4.8)
Medical Characteristics[e]		
Mean Duration Diagnosed with HIV, years (+/−SD)	13 (7.2)	14 (5.8)
Currently Prescribed Anti-Retroviral Therapy (ART)	21 (95.5)	20 (95.3)
Mean Duration since ART Initiation, years (+/−SD)	10 (6.0)	9 (5.6)

	Control Group (n=22)	Intervention Group (n=21)
	Frequency (%)[a]	Frequency (%)[a]
Undetectable HIV Viral Load	15 (68.2)	14 (66.7)
Median HIV Viral Load for those with detectable values/mL (IQR)	1,645 (780; 3,570)	19,065 (2,816; 155,000)
Mean CD4 cells/μ1 (+/−SD)	500 (261.1)	529 (309.5)
Have Comorbidities	18 (81.8)	20 (95.2)
Admitted to Emergency Department in Past 12 months	9 (42.9)	8 (38.1)
Admitted to Hospital in Past 12 months	4 (18.2)	5 (23.8)
Mean Percent Missed HIV Primary Care Appointments in past 12 months (+/− SD)	25.4 (27.2)	44.6 (35.3)

[a]Descriptive statistics are reported as frequency and per cent of total sample, unless otherwise noted; no statistically significant differences were found between the intervention and control group at baseline

[b]20 of 22 participants in the control group reported race;

[c]19 of 22 participants in the control group reported employment status;

[d]19 of 22 participants in the control group reported housing status;

[e]1 of the 22 participants in the control group did have a regular HIV clinic and we were not able to abstract these variables from their medical chart. For these variables, the denominator in the control group was 21.; Figure calculated as the number of appointments missed/total number of the primary care appointments schedule in the previous 12 months.

Table 2

Baseline and follow-up scores for outcomes by treatment assignment

Endpoints	Control (n=20)	Intervention (n=20)	Control (n=20)	Intervention (n=20)
	Baseline Sleep Outcomes		Follow-up Sleep Outcomes	
Mean Sleep Duration in hours(+/− SD)	5.5 (2.1)	6.5 (1.5)	5.6 ± 11.8	373 ± 74
Mean Sleep Efficiency % (+/− SD)	33.9 (14.9)	28.8 (11.4)	77.6 ± 11.7	82.1 ± 5.6
Mean Sleep Fragmentation % (+/− SD)	78.0 (13.1)	82.0 (8.7)	34.8 ± 16.3	29.5 ± 8.6
Mean Sleep Disturbances (+/− SD)	59.0 (9.5)	57.8 (5.9)	57.8 ± 5.9	57.4 ± 9.1
Mean Sleep-related Impairments (+/− SD)	55.8 (8.1)	53.0 (9.1)	50.4 ± 9.4	51.9 ± 9.0
	Baseline Quality of Life		Follow-up Quality of Life	
Mean Overall Functioning (+/− SD)	63.2 (18.7)	55.2 (23.4)	56.9 (19.4)	56.9 (18.3)
Mean Life Satisfaction (+/− SD)	73.8 (21.0)	65.3 (27.6)	71.6 (22.0)	70.3 (26.0)

[a]18 of 20 participants in the control group had complete data;

[b]19 of 20 participants in the control group had complete data

Table 3

Measures of Feasibility of the SystemCHANGE -HIV Intervention (n=20)[a]

Usefulness	Measure/Question	Result
	Attendance Rate at Sessions	71.4% of sessions attended
	Did you use what was taught?	Yes: 93%
	Was the program useful [b]	Good: 24% Excellent: 48% Superior: 29%
	Did you think it was worth your time? [b]	Good: 24% Excellent: 35% Superior: 41%
	Will you use the program in the future? [b]	Excellent: 6% Superior: 94%
Applicability		
	Overall satisfaction rating [b]	Good: 31% Excellent: 25% Superior: 44%
	Did you apply it to other habits?	Yes: 86% Including smoking cessation and job search
	What is the most important thing you learned?[c]	"[I really enjoyed] learning how to schedule time and apply myself more to do the things I have to do" "I learned that I can change and do better" "I can improve my health, sleep, and exercise" "Sometimes it's not always motivation that keeps you from reaching your goals"
Sustainability		
	Intervention Cost [d]	Total: $3731 or $186.56/per participant
	What participant's would pay for the intervention?	Mean if self-pay: $177 (+/− $222) Mean if insurance pay: $479 (+/− $386)

[a]17/20 Participants completed the final evaluation on which the self-report feasibility variables are based;

[b]Self-assessment on a 5-point Likert Scale where 1=Poor, 2= Fair, 3=Good, 4=Excellent, 5=Superior;

[c]Select representative quotes presented;

[d]Intervention costs include: Staff time spent contacting each participant X $15/hr; Staff time spent at each group session X $15/hr X 2 staff members; Compensation for participant travel and time /session; Food costs ~$10/session (not included were intervention development and training costs, opportunity costs for participants, staff time for data collection and analysis)

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Table 4

Mean change in outcome variables by treatment assignment (n=40)

Endpoint	Control Group		Intervention Group		Adjusted for baseline score and group assignment		Further adjusted for demographic variables[b]	
	n	Mean Δ (+/− SD)[a]	n	Mean Δ (+/− SD)[a]	Intervention – Control	p-value	Intervention – Control	p-value
Sleep time in minutes per night	20	6 (93)	20	−15 (94)	7 (−44, 59)	0.770	10 (−45, 65)	0.706
Sleep efficiency %	20	−0.3 (7.6)	20	0.1(9.7)	2.3% (−2.3, 7.0)	0.316	2.3% (−2.5, 7.1)	0.332
Sleep fragmentation %	20	0.9 (8.6)	20	0.7 (13.7)	−2.2 (−9.0, 4.6)	0.513	−2.0% (−9.0, 5.0)	0.568
Self-reported sleep disturbances	18	−1.3 (9.2)	20	−0.4 (12.5)	−0.4 (−5.6, 4.8)	0.880	−0.7 (−6.2, 4.8)	0.787
Self-reported sleep impairments	19	−5.5 (15)	20	−1.1 (13.7)	0.6 (−5.4,6.6)	0.839	0.5 (−5.8, 6.7)	0.876
Quality of life overall functioning	20	−5.4 (18.2)	20	01.7 (19.3)	3.6 (−6.7, 13.8)	0.486	−3.0 (−7.6, 13.6)	0.568
Quality of life satisfaction	19	−2.2 (21.3)	20	5.0 (32.5)	1.7 (−13.1, 16.6)	0.813	2.1 (−13.0, 17.2)	0.778

[a]Mean change from baseline to 10-week follow up;

[b]adjusted for age, sex, and yrs since HIV diagnosis