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Version 1
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IRB 2003012 Title Shared Decision Making to Improve Palliative Care in the Nursing Home

Protocol

Purpose

Our team is using web-conferencing technology to facilitate shared decision making (SDM) between families of hospice patients and hospice staff (1R01NR011472). Family members of hospice patients living in nursing homes in our current study suggested we translate this intervention to the nursing home.[10,20] Based on this family-identified need, this proposal facilitates SDM among family members, residents with serious illnesses (not enrolled in hospice), and the nursing home care team. Our overall research question (RQ) is: **What are the effects of a SDM process in care conferences via web-conferencing on family members and nursing home residents with serious illnesses?** Our overall hypothesis (H) is: **SDM among family members, residents (when possible), and skilled nursing home staff via web-conferencing will improve outcomes for family members and residents with serious illnesses**.

Objectives

1. To explore the experience of SDM for family, residents, and nursing home staff.
RQ 1. What are the facilitators and barriers to SDM in the nursing home?
RQ 2. What shared decisions will be made with family/residents during care conference meetings?
RQ 3. What concerns are communicated by families/residents to nursing home staff?
RQ 4. How will participation in web-conferencing impact the family/resident satisfaction with care?

2: To assess the outcomes of SDM using web-conferencing on families/residents.
H1: Family depression (Patient Health Questionnaire-9) will be lower in the intervention group than in the control group.
H2: Family burden (Zarit Burden Interview) will be lower in the intervention group than in the control group.
H3: Resident pain (Minimum Data Set 3.0) will be lower in the intervention group than in the control group.
H4: Family members' satisfaction will be higher in the intervention group than in the control group.
H5: The number of web conferences attended will be positively associated with improvements in outcomes.
H6: SDM instruments will demonstrate adequate reliability and validity within a nursing home setting.

Research Design and Method: We propose a P-RCT for this pilot study. Nursing home residents and their identified family member in one nursing home (The Bluffs) will be randomized into either an enhanced usual care group or an intervention group. Our purpose is to look at the intervention in a real-world context to allow evaluation of feasibility in the actual setting. This trial meets the definition of pragmatic because its inclusion criteria are broad, staff receive training in the intervention but are not required to strictly comply with every element of SDM in every conference, the intervention is applied by the entire nursing home team, the enhanced care training will be given to all clinical staff without restriction, the primary outcome is a clinically meaningful one, and the analysis will include all participants in an intention-to-treat fashion.[63,64] Enhanced usual care as a comparator is appropriate when the goals of a trial are pragmatic rather than explanatory.[65] Family in the enhanced usual care group will not participate in a SDM process but staff will be trained.

We will collect measures with families of both groups upon consent and every thirty days for a minimum of 90 days and a maximum of 240 days, depending upon the length of time they are enrolled in the study before data collection is concluded. Resident measures will be recorded following each MDS assessment. We will recruit 23 residents and their family members in each group for a total sample of 46 residents and 46 family members (See Section D.7.2.1). If more than one family member enrolls then we will need fewer residents, as our total of 46 family members will be reached more quickly. Inclusion/exclusion criteria are summarized in

Table 2 and explained fully in Section E. Family members will be identified by either the residents or the nursing home staff; a resident may have more than one family member enrolled. Based on intervention trials in the nursing home,[19] we will assume a 15% attrition rate (Section D.7.2.1). Nursing home staff will also be research subjects and will assist in the evaluation of the intervention through qualitative interviews. The analysis of care conferences will include video-recording staff interactions, and a final interview to assess staff satisfaction with the project. We will interview 5 staff in each year of the project for a total of 10 interviews.

Intervention: The purpose of our intervention is to enable and facilitate family member involvement in care planning conferences with a SDM process. Web-conferencing technology will enable remote participation. Based on experience from our preliminary work (publication in review), a SDM process will be incorporated into the care plan meeting to facilitate meaningful involvement. We will use VSee as the web-conferencing software. VSee uses open industry standard, FIPS 140-2 compliant 256-bit AES encryption on all control and media traffic. Only the people participating in a conversation can decrypt data passed through VSee conversations.[66] VSee is often referred to as "telemedicine" videoconferencing tool and has been endorsed by numerous health care systems and organizations throughout the country (including Stanford Hospitals and Clinics, Trinity Health, Intermountain Healthcare etc). (http:vsee.com). See Section E.

Intervention Group: Per regulation, residents will continue to be encouraged to attend their care conferences on-site, as is the current standard of practice. At least one member of the research team will be on-site for each care conference to facilitate the technological aspects of the intervention. Family members in the intervention group will use a web-enabled device (computer, smartphone or tablet) to virtually participate in the care conference. To prepare family members for the intervention, we will produce a short video that will train family members on the use of VSee, provide an overview of care planning conferences, offer recommendations to enhance web-based communication, and discuss the process of shared decision-making. A member of the research team will contact each participating family member at least 24 hours prior to the scheduled care conference to confirm their participation, answer questions, and provide an approximate time the nursing home team will be contacting them to initiate the web-conference. Time zone differences will be considered in the scheduling when possible. In addition, the research staff member will have a cell phone on-site during the care conference to allow the team to contact the family member via phone if necessary to provide just-in-time instruction on the use of the web-conferencing technology, as needed. Our team's five years of experience facilitating web-conferencing between families and health care teams in non-nursing home settings have allowed us to develop these procedures, which have been successful. After successful contact with the family member, research staff will take on the role of observer, completing detailed field notes during each care conference. In addition, research staff will video-record a sample of 4 conferences per month (76 total) to allow for detailed analysis of the conferences. All clinical staff will attend a quarterly SDM training session, will be given reference cards outlining the SDM process, and a poster with the elements will be placed in the conference room for reference. Staff will be trained to use the SDM process when interacting with family or residents, however, given the pragmatic nature of this study, staff will be encouraged and supported to use the SDM process but not required to do so.

Enhanced Usual Care: Usual care will be enhanced with the training provided to all clinical staff in SDM. Family members assigned to the enhanced usual care group will not be involved in the web-conferencing and are by definition of the inclusion criteria unable to attend the care conference. They will not be offered web-conferencing access to the care conference. Interactions among the family member, resident, and staff will not be scheduled, initiated, or facilitated by the research staff. Research staff will observe care conferences for enhanced usual care participants to compare staff behaviors and attitudes.

Data Collection: Research staff will contact family members in both the intervention and enhanced usual care groups every 30 days to collect data using the same measures (Table 3) for both groups. Additionally, for both groups, research staff will extract selected elements (Table 3) from all MDS assessments completed during a resident's participation in the study. Finally, family members and residents (when able) in both groups will be interviewed following study completion using a semi-structured interview guide. A sample of facility staff will be interviewed each year of the study. See Appendix.

Consent/enrollment: The study will be presented to nursing home staff in a staff meeting. A special effort will be made to promote attendance at a resident/family council meeting to explain the study, obtain resident feedback and promote enrollment. Brochures will be developed to encourage participation and referral. Similar to our prior work, nursing home staff members will identify residents who meet the study inclusion criteria and

request verbal permission from residents or their family members to provide their contact information to the research team.[46,67]

Protection of Human Subjects
Human subjects will include nursing home residents, their designated family member(s), and nursing home staff. The total participants for this trial will be 102; 46 residents and 46 family members (23 residents and 23 family in each group) and approximately 10 nursing home staff. The participants must meet inclusion criteria to ensure the effectiveness of the intervention and reduce any potential risks or burdens to them.

Family Members
Family members will be the primary focus of the research and primary pool of research subjects. **The first criterion** is that they be identified by the nursing home resident or nursing home staff as a family member or significant other of a resident at The Bluffs. **A second criterion** is that the family member must be over the age of 18 to formally consent to participate in the study. Although 18 is considered a child by NIH, it is the minimum age for proxy decision-making in the state of Missouri. **Thirdly,** the designated family member must not have a cognitive impairment that interferes with their ability for shared decision-making on behalf of the resident. This will be determined by the nursing home staff. **The fourth criterion** is that the family member has access to a computer, tablet, or smartphone device that supports web-conferencing. The pilot nature of this project and the budget limitations prevent us from providing this technology to family members. While research in technology continues to show the increased access to these technology resources,[37] we appreciate that not all families may have access. One of the secondary outcomes from this pilot will be determining the degree to which Internet and technology access is an issue. If access to technology is an issue in this pilot, a plan will be created and budget will be available in the follow-up trial for affordable solutions permitting access and participation. **The fifth criterion** is that the family member is otherwise unable to attend the care conference onsite at the nursing home due to travel distance, employment restrictions, etc. The intervention is focused on allowing those who would otherwise be unable to participate in care conferences the opportunity to do so. Should a family member's situation change and they become able to routinely attend conferences in person, they will be dis-enrolled from the study as they no longer would meet this criterion.

Residents
The **first criterion** requires that a nursing home resident live at The Bluffs nursing home. **The second criterion** requires residents be at least 65 years of age. Currently, the majority of nursing home residents are over 80 years of age. Seniors are the focus of the NIH Program Announcement (PA 13-355) for this proposal to improve geriatric palliative care. **A third criterion** is that the resident has at least one family member or significant other who will participate in the shared decision-making process. **The fourth criterion** requires that the resident, as determined by the nursing home staff, has a serious illness, making them appropriate for palliative care.

In addition to these four inclusion criteria, there are two criteria that will exclude residents from the study. **The first exclusion criterion** involves residents who are admitted to the skilled nursing facility for short-term post-hospital care with the goal of returning home. These residents do not represent the long-stay nursing home population, and their length of stay in the nursing home will not allow for evaluation of the research questions or testing of the hypothesis. **The second exclusion criterion involves residents enrolled in hospice care at the time of study enrollment**. The Program Announcement (PA 13-355) supporting this proposal specifically excludes hospice patients from the available funding. If a study resident enrolls in hospice while already enrolled in our study, they will not remain in our study.

Residents with cognitive impairment may participate in the study. We will use a reasonable person approach to determine a resident's understanding of the research. As a low risk study, this approach allows us to determine if the resident seems to grasp the concepts of the study and determine if their responses are appropriate and make sense. Dr. Popejoy has used this approach previously. If the research specialist in consultation with the nursing home staff evaluate the resident and determine they understand the concepts of the study, they will be asked to sign a consent form. If however the research specialist and nursing home staff to not believe the resident can understand the study, then their surrogate decision maker or designated family member will be asked to consent on their behalf.

Nursing Home Staff
Finally, nursing home staff will also be study subjects. As residents and family members become more

active in the decision-making process, staff may need to change their behaviors to support the process changes. [42,43] Thus, the comprehensive evaluation of the SDM intervention we propose will examine outcomes not only for residents and family members, but also for the nursing home staff involved in the project. The **first criterion** will be that they are employees at The Bluffs nursing facility. We will observe and video-record the staff during their interactions with residents and families during the care conferences. All nursing home staff involved in the project will be asked to sign a consent form to participate. While involvement in the care conference and addressing family issues is a part of the nursing home residents' bill of rights and the staff members' job descriptions, they are not required to be video-recorded or interviewed. We have successfully addressed this issue in our preliminary work[38] and have outlined this process in the consent section below. **The second criterion** requires staff to be over the age of 18, the youngest age that a staff person may be employed in a nursing home. **Finally,** staff must hold a position which makes them a part of the care team and a participant in the care conference or direct care of a resident (aide, nurse, social service, dietary, etc.)

Protection against risk

Resident and family confidentiality and comfort with the technology are protected, for they must agree before a web-conference connection is made. We have chosen the videoconferencing solution called VSee (Vsee Inc, Sunnyvale, CA) which is free to download and use for both personal and commercial use (similar to Skype). While both Skype and VSee are free videoconferencing systems, VSee is considered more secure. VSee uses open industry standard, FIPS 140-2 compliant 256-bit AES encryption on all control and media traffic. Unlike Skype, VSee uses RSA public/private key to exchange the AES session key such that the VSee servers do not have access to the AES session key. For this reason, VSee is often referred to as "telemedicine" videoconferencing tool and has been endorsed by numerous health care systems and organizations as a videoconferencing tool throughout the country (including Stanford Hospitals and Clinics, Trinity Health, Intermountain Healthcare etc.) (http:vsee.com). VSee uses open industry standard, FIPS 140-2 compliant 256-bit AES encryption on all control and media traffic. Unlike Skype, VSee uses RSA public/private key to exchange the AES session key such that the VSee servers do not have access to the AES session key. This means only the people participating in a conversation can decrypt data passed through VSee conversations (whereas Skype has the ability to monitor individual conversations).[66] In a study by the Office of High Performance Computing and Communications at the NIH National Library of Medicine, investigators concluded that "VSee provided secure encrypted video that looked superior to other low-bandwidth products." [66]

A leadership resource at MU provides us with an additional layer of protection. Our Senior Associate Dean for Information Technology has a background in information security, and assurance of data security is part of her role. Finally, all resident/family information taken from the nursing home will be "de-identified" with a coding schema rather than names. All research data that leave the nursing home will be maintained in a locked file cabinet in the PI's office. No transcription shall contain the name of a resident, family member or staff member.

Consent and Enrollment

Upon referral from the nursing home staff, research staff will contact the resident or his/her family member surrogate decision-maker, explain the study, enroll the resident, and identify appropriate family member(s) to participate. Residents will be randomized and family members will receive the same group assignment as their resident. Family member(s) will be referred by the resident, nursing home staff, or other family members. More than one family member may participate, and all members of the same family will be assigned to the same group. Participating residents who are able to sign a written consent form will do so (see Section E.1.2 for protocol with impaired residents), and baseline measures for residents will be obtained from the most recent MDS. Enrollment will not be considered final until we obtain the written consent of both resident (or his/her surrogate decision-maker) and family member. Following consent of the resident/surrogate, research staff will contact the family member(s) identified as potential study participants (if different than the surrogate), explain the study, and obtain oral consent for their participation. Family members will be asked to go to a secure website to electronically sign a consent form as approved by MU HSIRB. Nursing home staff consent will be obtained for anyone involved in care plan meetings. Nursing home staff will sign a consent form that will permit video-recording of their participation in care conferences and audio-recording of their follow-up interviews. In our previous work we have had no staff members opt out of any aspect of the study. Draft consent forms are in the Appendix.

We anticipate that 10 nursing home staff will be involved in the study. We will observe and randomly video-record staff as they interact with families during team meetings. As in our preliminary study, all staff members

will be asked to sign a consent form with three levels of consent (see appendix). We recognize that coercion is a potential issue and have developed a plan to address the concern. The consent process is designed so staff members have time decide whether and how much to participate. Our Research Specialists will meet individually and privately with each staff member during the consent process or during their orientation to the nursing home. Research Specialists will explain the study and consent without making the administration or other staff aware of who has and has not consented.

Because staff must participate in care plan meetings as part of their job, study consent involves (1) being video-recorded in care plan meetings, (2) having their image appear on the Internet and, (3) participating in a post-study interview. During our preliminary trial, all of the 115 hospice staff approached consented to all three options. Staff members do not need to consent to participate in the study to participate in care plan meetings. In recognition of staff members' right not to participate in the study, we have developed a multi-level consent process, allowing them to specify their involvement. The staff consent form will designate each option separately and will be kept confidential. Should a staff member refuse to be recorded during care plan meetings and communications with family, then those family will not be among the cases we record (we will video record a 25% subsample of family in both groups per quarter). Should a staff member refuse to have their image displayed on the Internet, they can choose not to sit in sight of the camera and thus prevent the image from being sent to the family. They also can decline to be interviewed post-study. Research staff will know the individual conditions of staff consent but other nursing home staff and administration will not. In appreciation for the staff time and commitment, we will issue tickets for an annual lottery drawing held in each agency. The winners will receive $100 cash.

Potential Benefits of the Proposed Research to the Subjects and Others

The proposed project can improve nursing home services by empowering family members to be more actively involved in the care of their loved one. The web-conferencing technology allows family to participate in the nursing home care discussions and express their concerns, goals, and values as the plan of care is developed and modified.

Importance of the knowledge to be gained

This project will evaluate the value of family members formally participating in the development and delivery of care to their resident in a nursing home, and sharing in decisions related to that care. The underlying concept is that, with the help of the web-conferencing to bridge geographic distances, family can enter into discussions related to resident needs and ensure that the care and decisions made align with the resident values/beliefs/goals. The knowledge gained from this project will allow the research team to develop a future study that utilizes the intervention in more homes and potentially across various long-term care settings.

Data Monitoring Plan

Data will be collected using standardized paper forms and will only be identified with the study's arbitrary ID number for the participant. Codes that link the name of the participant and the study ID will be kept confidential in a secured cabinet. Collected forms will be transported to the PI's office once per week for permanent storage in a locked office. The research staff will enter data from the forms into the electronic database. The data manager, based on source documents, will report apparent data discrepancies and seek staff input for correction. Data and protocol concerns will be addressed through the research team. Larger concerns with the protocols may be forwarded on to institutional committees depending on the severity of the issues. Fidelity of the intervention will be monitored through quarterly observations by the PI or her designee and through ongoing qualitative analysis of video recordings. Data quality will be monitored by random inspection of the completed forms by the data manager, and any problems detected will be discussed with the PI and research team.

Safety Monitoring Plan

During screening, study applicants will be assessed to determine their eligibility and safety of their participation in this study. Research staff will collaborate with the nursing home nurse to assess the appropriateness of the resident and their alignment with the inclusion/exclusion criteria. We will use the HSIRB definition of serious adverse events (SAEs). The IRB understands that this definition is unusual in nursing homes and with residents with serious illness, where deaths are not considered an SAE because death is not unexpected. Any SAE related to the study intervention will be reported to the IRB. The initial SAE report will be followed by submission of a completed SAE report to the MU HSIRB. Outcomes of SAEs will be reported periodically to

NIH. A summary of the SAEs that occurred during the previous year will be included in the annual progress report to NIH.

Measures

Table 3: Summary of outcomes (reference), instruments, measure frequency	
Outcome Variable	**Instrument and Description**
Family member depression [13,47] Collected every 30 days	Patient Health Questionnaire (PHQ-9).[68] Family members indicate the frequency of symptoms of depression; higher scores reflect higher depression severity (9 items). Internal reliability Cronbach's alpha = 0.89.
Family member burden[13] Collected every 30 days	Zarit Burden Interview.[69] Family members indicate the frequency with which their responsibilities to their resident are perceived as burdensome; higher scores reflect higher burden (22 items). Internal reliability Cronbach's alpha = 0.86.
Family satisfaction with nursing facility [37] Collected every 30 days	Nursing Facility Family Satisfaction (NF-FSQ).[70] Family members indicate their level of satisfaction with various domains of the nursing facility (23 items). Cronbach's alpha for all domains > 0.70.
Resident pain [47] Collected with new MDS	Minimum Data Set 3.0 Pain (Section J).[71,72] Standardized tool used quarterly (or more often for a significant status change) to assess every resident in the nursing home.
Shared Decision Making PICS collected after each care conference; LACTonII collected for staff annually	PICS (Patients Perceived Involvement with Care Scale).[73] 20 items to assess the perceived involvement with care. 4 subscales: Provider information, family information, family decision-making, and provider facilitation. Reliability= .79-.89 LACTon II[74] (Leeds Attitude Concordance). 20 items to identify attitudes of health care providers towards patient partnership. Reliability .82
Qualitative and Co-Variate Data	
SDM during care conferences	Video-recorded care conferences will be analyzed to explore family involvement in shared decision-making. Four sessions per month will be video-recorded (total of 76).
Family, resident, and staff satisfaction with the intervention	Individual interviews will be conducted with family members, residents, and nursing home staff. Interview data will be analyzed to examine participants' satisfaction with the intervention.
Technical quality	A structured field note will provide a summary of each web-conference encounter and an assessment of technical quality.[75]
Demographic variables	Demographic data include the date of admission to the nursing home, family distance from nursing home, number of care conferences previously attended (as reported by family), frequency of resident/family contact (as reported by the family), resident and family member age, resident diagnoses, and relationship to the resident.

Qualitative analysis: Qualitative analysis will proceed simultaneously and continuously with data collection, allowing for pertinent revisions to be made to the observation protocol and interview guide as the study proceeds.[77] Researchers will begin analysis by applying codes to segments of data that address the study research questions (Table 4). Early coding will be guided by the initial coding framework detailed in Table 4; however, the framework will be refined and expanded as needed during the process of data analysis. Researchers will use NVivo 10 software, which permits direct coding of audio and video files, eliminating the need for transcription. After agreement has been reached on the final coding framework and corresponding definitions, two investigators will code the same data files (which will comprise 10% of the full data set) and use NVivo 10 to calculate a Kappa statistic for inter-coder reliability. If inter-coder reliability is 80% or greater, they will divide the remaining files and independently code the remaining data. If inter-coder reliability is less than 80%, they will repeat co-coding with an additional 10% of the data files, repeating this process until satisfactory reliability is achieved. A coding matrix summarizing data for each research question will be generated.

Table 4: Initial coding framework by research question	
Research Questions	**Initial Codes**
1. What are the facilitators and barriers to SDM in the nursing home?	Facilitators/barriers will be identified for each of the 9 steps of SDM.[41]
2. What shared decisions will be made with family/residents during care conference meetings?	Decisions regarding: 1) nutrition, 2) infections, 3) pain, 4) shortness of breath, 5) behavioral issues, 6) hospitalization, 7) other (specify and memo for potential modifications to framework).[76]
3 What concerns are communicated by families/residents to nursing home staff?	Family/resident expresses concerns related to 1) communication problems, 2) resident care concerns, and 3) pain management.[9]
4. How will participation in web-conferencing impact satisfaction with care?	Content analysis of interviews will inform the coding process as codes emerge from the data.

Sample Size/Power Analysis: Staff-family relationship quality, specifically conflict, has been found to be significantly associated with family caregiver depression.[78] **We will therefore power the proposed intervention from the PHQ-9, which measures family member depression.** While the aim of this pilot study is to test the outcomes of the intervention in preparation for a larger trial, we rely on the literature and our preliminary data to determine a sample size for this study. The PHQ-9 is measured on an integer scale with a range of 0 to 27, with higher scores indicating greater depression.[68] The null hypothesis is that the mean PHQ-9 score will not differ between the Enhanced Usual Care and Intervention groups. Although we anticipate that the mean PHQ-9 will be higher for caregivers in the Enhanced Usual Care group than in the Intervention group, indicating that the intervention lowers caregiver depression, we will power the study using a two-tailed test of significance, allowing the detection of a significant difference in either direction. The sample size calculation is based on a two-tailed test of significance and the following assumptions: (1) the expected difference in PHQ-9 means between enhanced usual care and intervention groups is 5 points, the documented clinically significant effect;[78] (2) based on our preliminary work with hospice caregivers the variance of scores is 5.33; (3) error protection: $\alpha = .10$, $\beta = .20$ (given this is a preliminary trial) [79] and, (4) anticipated attrition of 15% as indicated in similar end-of-life intervention studies in the nursing home setting. [19] **A sample of 23 residents and 23 family members per group (46 total family and residents, total of 92 participants) will provide 80% power to detect the 5-point difference in the PHQ-9 scores.**

Statistical Analysis: Basic descriptive statistics including the range, mean, median, and appropriate measures of precision will summarize demographic and baseline data. We will test whether randomization created balanced groups by comparing baseline measures and demographic characteristics using chi-square or t-test analysis for categorical or continuous variables, respectively. If any variables differ significantly between groups, they will be included in regression models as potential confounders. **For H1-4** we will compare outcomes using a mixed model for repeated measures of each outcome variable that includes TIME (baseline, 30 days, 60 days etc.), GROUP (intervention, enhanced usual care), and a TIME x GROUP interaction term, along with potential confounding variables as covariates. We will use SAS PROC MIXED because it is known to be robust for missing values. The MIXED procedure will allow us to model the correlation between the repeated measures over time in a variety of ways, the simplest being autocorrelation or order 1 (AR1). In this analysis, the main effect of GROUP will be treated as the average effect; the main effect of TIME will be treated as a trend; and the interaction indicates whether the trends differ between groups. Least Squares Means will be used to compare groups. Residuals from this model will be examined for normality. If residuals show non-normality, we will explore log-transforming the outcome variables or using nonparametric methods such as the Wilcoxon Rank Sum test or the Cochran-Mantel-Haenszel test. **To test H 5,** we will use a regression model from the Poisson family that will account for varying rates of exposure with a clustered sandwich estimator to account for the dependency in the data. For example, we will use a negative binomial regression if there is overdispersion in the variation of the Poisson distribution. We will use zero-truncated negative binomial regression if there is overdispersion and zero truncation for the outcome, the number of web conferences attended. For these models we will use SAS PROC NLMIXED, will check model specification using regression diagnostics, and compare the various models with AIC and BIC values to ensure correct model choice. Analyses will be conducted under the intention-to-treat principle – all participants randomized to a group will be included in the analysis regardless of their level of participation. SAS 9.4 (SAS Institute, Cary, NC) will be used for all data analyses**. H 6** data analysis will be guided by the NIH patient-reported outcomes measurement system analysis plan[80] including: (1) Item and scale analyses to include an inspection of response frequency, mean, standard deviation, range, median, interquartile range, inter-item correlation matrix, item-scale correlations, and coefficient alpha; (2) Descriptive statistics to characterize the

sample demographics for item and questionnaire nonresponses. Depending on the prevalence of item nonresponse, missing data may be handled by excluding items, imputing responses using mean substitution, a mixed-model approach, or multiple imputation prior to factor analysis; (3) Evaluation of statistical assumptions of classical test and item response models to include the unidimensionality, local independence, and monotonicity assumptions; (4) Estimate CFA and IRT model parameters; and (5) Use of the Cochran-Mantel-Haenszel test to identify potential differential item functioning between socio-demographic groups.

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