FitSitt Phase I SBIR Protocol

*Black highlighted text within the body of each section contains confidential, proprietary information belonging to Activ Sitting, Inc. This cannot be shared publicly and thus is redacted.

STUDY TITLE:

Toward development of a comprehensive, in-home, active seating system to lessen sedentariness and improve health and wellness in older adults.

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STUDY PROCEDURES

1. Background/Rationale

Older adults spend 80% of their day sitting (Matthews et al., 2008; Stamatakis et al., 2012). Given the strong link between inactivity and lifestyle-related diseases (Biswas et al., 2015), the economic burden of sedentariness is high: $117 billion of annual United States healthcare costs can be attributed to inactivity (Carlson et al., 2015). There is growing interest in bolstering older adults' activity patterns by decreasing prolonged sedentary activity (Gennuso et al., 2013; Martin et al., 2015). Whereas the evidence base addressing theory of and methods for improving physical activity is vast, much less is known about how to intervene on patterns of sedentariness. Important to consider are the wide-ranging barriers older adults encounter to reducing immobile time such as lack of convenient options (Beck et al., 2016; Mathews et al., 2010; Witcher et al., 2007), limited self-awareness about one's own activity patterns (van Uffelen et al., 2011), low motivation (Baert et al., 2015; Bethancourt et al., 2014), and fear of being injured (Baert et al., 2015; Rasinaho et al., 2007).

Targeting activity patterns even in late life is a viable option to slow progression from health to disability (Berk et al., 2006; Buchman et al., 2012; Sun et al., 2010), and engaging in even light physical activity can beneficially affect psychosocial health, glucose metabolism, lipid status, and mortality (Bertheussen et al., 2011; Fuezeki et al., 2017; Kim et al., 2012). An innovative way to tackle inactivity consists of altering older adults' "sedentary space" in which they spend their time (Chastin et al., 2015). The *Activ Sitting*-USC team proposes to develop a [redacted] It can be easily integrated into older adults' living spaces and everyday routines, maximizing potential for long-term adoption and use. A safe and practical activity-promoting solution for older adults to access in-home, like *FitSitt*, is needed now more than ever in the wake of COVID-19, especially given the pandemic's consequences on people's capacity to lead an active lifestyle (Woods et al., 2020).

2. Purpose/Objectives/Aims/Research Questions

This study had two primary specific aims and associated milestones:

1) Build an enhanced *FitSitt* system prototype that includes specialty features and is suitable for user testing.
   - Milestone 1: develop a specifications report for new *FitSitt* features.
   - Milestone 2: build one operational *FitSitt* system compliant with Milestone 1 specifications.
   - Milestone 3: produce the first version (v1) of a Failure Modes Effects and Criticality Analysis (FMECA) report.

- Milestone 4: take corrective actions by reducing critical indices of failure modes to "acceptable" or "consideration" levels or removing them from the system.

2) Assess the initial feasibility, acceptability, and safety of the enhanced *FitSitt* system with target users.
   - Milestone 1: collate and categorize available mixed-methods data as process, functionality, hardware, or software information for analysis in a second FMECA cycle.
   - Milestone 2: produce a v2 FMECA report that details the necessary corrective actions, and who will take them, to move failure modes into acceptable criticality levels.

The protocol included for clinicaltrials.gov reporting here only contains information relevant to the in-home testing phase of the overall study given this is the only phase that involves a clinical trial.

3. Participants

3.a. Inclusion and exclusion criteria

In-home Testing Stage

Inclusion criteria

(1) Age 65 years old or older
Justification: the target consumer group for *FitSitt* is older adults.

(2) English-speaking
Justification: we will not have personnel available for language translation.

(3) Live in local Los Angeles area and no plans to vacation away from home during the trial period
Justification: research staff will not have the resources to travel outside of the local LA community. Vacation away from home would artificially reduce time spent using the *FitSitt* during the brief trial period.

(4) Self-reported ability to safely engage in 30 minutes of light-intensity activity per day
Justification: this criterion is indicative of a person's basic health status and ability to tolerate use of *FitSitt* without exacerbating health conditions.

(5) Self-reported ability to pedal comfortably without stopping for 5 minutes
Justification: this criterion is indicative of a person's basic health status, minimum physical capacity, and ability to tolerate use of the *FitSitt's* treadles without exacerbating health conditions.

(6) Community-dwelling
Justification: *FitSitt* requires testing in a relatively healthy population first, despite there likely is future application for older adults who are institutionalized.

Exclusion criteria

(1) Dependence in transferring to a chair safely
Justification: this criterion requires an individual to have a sufficient level of function to safely use the chair.

(2) Inability to safely and reliably access and operate *FitSitt* (ascertained by a brief demonstration at beginning of in-home visit)
Justification: this will help to ensure we will receive necessary data to study usage patterns and user satisfaction.

(3) A member living in the same household participated in the in-home testing stage of this study
Justification: the study requires diverse perspectives about the prototype to be tested in-home. A member of the same household having already tested the prototype may unduly influence the individual's own perspective or may have very similar feedback to the other participant.

(4) Participated in the in-lab testing stage of the study already
Justification: this criterion helps to ensure we have a diverse pool of perspectives gathered from participants at each stage of the prototype testing.

(5) Unstable health conditions such as uncontrolled blood pressure, end-stage renal failure on renal replacement therapy, or malignancy currently on chemotherapy.
Justification: this criterion is indicative a person's basic health status and ability to tolerate use of *FitSitt* without exacerbating unstable conditions.

3.b. Rationale for excluding children

Children are excluded from this study because we are developing a seating system tailored specifically to older adults. The system itself is also designed for adult sized anthropometrics.

3.c. Special subject population

The study participants are not a part of a special subject population. Participants are generally healthy, community-living older people.

4. Recruitment/Screening Process (sampling strategy)

4.a. Recruitment Locations/Sources

- USC Healthy Minds Research Volunteer Registry healthyminds.usc.edu
- Collaborative Approach for Asian Americans & Pacific Islanders Research & Education (CARE) Registry
- Word of mouth/personal solicitation
- Flyering
- Tables at community events/venues
- Website (e.g., Keck Medicine of USC Clinical Trials website) and social media postings (e.g., Nextdoor)
- Emails to participants in a previous study (HS-16-00670) that was led by PI Schepens Niemiec
- Front Porch Center for Innovation and Wellbeing recruitment support

4.b. Recruitment Methods

We will use a multi-faceted recruitment approach for the proposed research. We will recruit 15 participants for co-design workshops featured in Aim 1, as well as 30 + 15 participants for an in-lab and a three-day in-home testing period for Aim 2, respectively. We will aim to enroll participants in a way that is representative of LA County: ~32% (n=19) non-White, ~48% (n=29) Latino/Hispanic, and ~57% (n=34) female. We will also aim for representation from both age groups (roughly equal representation from either group) and by level of sedentariness (i.e., watch <2 hours of TV per day on average [~45% representation] vs. watch >2 hours of TV per day on average [~55% representation]). Recruitment will take place using the following sources and methods:

USC Healthy Minds Research Volunteer Registry – potential participants will be identified through purposive sampling using the USC Healthy Minds Research Volunteer Registry healthyminds.usc.edu, which will serve as our primary recruitment source. Additional recruitment strategies and sources will be activated should this primary recruitment means fall short of our recruitment goals and timeline. The Healthy Minds registry houses the Healthy Minds Volunteer List of older adults who have previously expressed interest in research on aging. This list can be accessed by research groups who pay an annual subscription and proof of IRB approval.

Once made available, the research team will export the volunteer list to Excel, and sort it by age group (65–84, 85+), sex (male, female), and race/ethnicity. Participants will be purposively selected and contacted from the stratified Healthy Minds Volunteer List to be screened and enrolled, should they meet necessary eligibility criteria, fulfill purposive sampling requirements, and have interest in participation. Imbalance of participants from any of the categories will be remedied by reaching out to only selected individuals who are from any of the underrepresented groups, and/or enrolling only a

fraction of individuals from an overrepresented group. Additional Healthy Minds recruitment script content (in phone-ready format) will be added to the standard recruitment script included in our screening form and as a part of an email script for Healthy Minds volunteers. The Healthy Minds registry also has a website for registrants on which brief descriptions of participating studies are included.

Collaborative Approach for Asian Americans & Pacific Islanders Research & Education (CARE) Registry – this registry houses a list of volunteers who identify as Asian or Pacific Islander with an interest in health-related studies across the lifespan. The research team will submit an application to the CARE team that describes the study and eligibility criteria, and show proof of IRB approval. Should the CARE team approve the application, they will run queries of their registry with the study's basic eligibility criteria like age and language spoken. A list of contacts who fit these criteria will be passed from the CARE team to the research team to recruit. Additional CARE Registry recruitment script content (in email-ready and phone-ready format) will be added to the standard recruitment script included in our screening form.

Word of mouth/personal solicitation – we will engage in word of mouth/snowball sampling, a chain-referral method where participants will refer individuals to the study team who are not part of the same household (see in-lab and in-home testing exclusion criteria above). The study team will also spread the word about the study through their personal networks.

Flyering – we will post flyers around the local community and attach them electronically to any word-of-mouth outreach communications that happen over time. If individuals see a flyer, they will have the team's contact information to reach out to the study team.

Tables at community events/venues – the study team will go out into the community to host information tables at various events or venues that attract older adults (e.g., senior community centers, senior living facilities, health fairs). Staff will be available to make a brief presentation about the study if requested by the venue, to answer questions about the study for interested individuals, and to hand out recruitment flyers.

Websites/Social media outlets –We will utilize various websites for study recruitment. We will post an ad on the Keck Medicine of USC Clinical Trials website, which includes a listing of any clinical trial available at USC. Content to be posted on the site must first be approved by IRB. Once published, individuals can read about the study and provide their contact information on a fillable form on the site. A notification is sent to the study team with that person's contact. We will also post a very brief summary of the study on the Chan Division website that will link to the Keck Medicine of USC Clinical Trials website for more information. Contact information will be made available for individuals to reach out to the study team. Finally, we will post advertisements of the study on social media apps like Facebook, Instagram, and Nextdoor.

Front Porch Center for Innovation and Wellbeing (FPCIW) – we will engage our community partner, FPCIW, as needed if other recruitment methods are not sufficient. Grant funds have been allocated to offset FPCIW's costs in the event we require their recruitment assistance. They would send flyers to their senior living communities and make announcements at their facility events.

4.c. Recruitment Materials

A number of materials will be used for recruitment including the following:

Screening, contact, and referral form – [document "Screening Contact Referral Form FitSitt SBIR Ph1" in iStar 24.2] – this form will be used for all prospective participants regardless of how contact information was obtained. It includes a recruitment script—one appropriate for each stage of the study and selected based on enrollment needs—at the beginning to use for interested individuals who contact the study team about participation. The form also includes a consent to retain screening data as described in 4.d below. The form will be used to gather demographics, general health, and additional information to determine eligibility. Contact and referral information is stored securely on REDCap such

that personally identifying information linking participant to study ID is only seen by authorized research personnel—a setting in REDCap will be used to indicate protected information.

Flyers – [documents "Flyer FitSitt SBIR Ph1 [*style of flyer labeled here in file name*]," in iStar 24.2] – various versions of a recruitment flyer will be used such as ones that have a "techy" style, ones with and without pull tabs, and ones geared toward a younger audience who could use word-of-mouth to inform older individuals.

Website/social media advertisements – [documents "Keck Clin Trial Web Ad" and "Chan Website Recruit" in iStar 24.2] – these website advertisements will include a description of the study and a contact information individuals can use to reach the study team. For social media websites like Facebook, Instagram, and Nextdoor, we will utilize the approved content (images and text) from the submitted flyers above.

Registry/database/study-specific recruitment – For individuals identified through the CARE Registry or the Healthy Minds Research Volunteer Registry, we will use a phone-ready recruitment script that is embedded within the general screening script [document "Screening Contact Referral Form FitSitt SBIR Ph1" in iStar 24.2]. See sections in the Introduction segment that refer specifically to CARE or Healthy Minds. Additionally, we will use an email-/postal mail-ready script to reach out to participants digitally or through US Mail [documents "CARE FitSitt Mail Recruit" and "Healthy Minds FitSitt Mail Recruit" in iStar 24.2]. The letter includes a description of the registry from which we obtained their contact, as well as a description of our study and necessary contact information. A brief study description [document "Healthy Minds Site Blurb" in iStar 24.2] will also be posted on the Healthy Minds registrant website.

4.d. Screening Process

If a potential participant responds to any of the aforementioned recruitment methods, they will be screened for eligibility using a study-specific questionnaire [document "Screening Contact Referral Form FitSitt SBIR Ph1" in iStar 24.2] via telephone or in person. MPI Schepens Niemiec will determine final eligibility in any case where suitability for the study is unclear. At the beginning of the screening process, the potential participant will be guided through a brief screening consent to request permission to retain screening data for future use. This screening consent includes a brief description of the study, what will be done with screening data if individuals are eligible/ineligible and if they are eligible those data will be linked to their main study data if they decide to participate. Should an individual decline to provide screening consent but would like to continue through screening, the study team will complete the screening but will make note the individual's information cannot be retained for future use with the main study. Screening data will be entered into REDCap for storage. To reduce screening burden for prospective participants, we are requesting an Alteration of the Required Elements of Consent for the Screening Consent. The elements being waived are:

- A description of any reasonably foreseeable risks or discomforts to the participant.
- A description of any benefits to the participant or to others, which may be reasonably be expected from the research.
- A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
- A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained.
- An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights, and whom to contact in the event of a research-related injury to the participant.
- A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and the subject may discontinue

participation at any time without penalty or loss of benefits to which the participant is otherwise entitled. (The consent says participation is voluntary, but the rest of the text is waived).

5. Methods

5.a. Detailed description of the project

5.a.i. Step-by-step methods

Recruitment, Screening, and Informed Consent Procedures

Recruitment and screening procedures are detailed in section 4.b and 4.d of this document, respectively. Informed consent for the study will take place using the following procedures. If a person fully meets eligibility criteria as determined through screening and continues to express interest in enrollment following screening, an informed consent session will take place either immediately or will be scheduled for a future time, depending on the individual's preference/ availability. The consent process will take place either remotely through digital consenting available from REDCap or in person. In all cases, informed consent will be obtained only by authorized, trained study personnel affiliated with USC and not by employees of *Activ Sitting, Inc.* to avoid conflict of interest. Each prospective participant will be given time to read the consent and discuss their options with project staff and family members. To ensure ample time to peruse the consent information, we routinely mail or e-mail copies of a sample informed consent document to each interested party. When the prospective participant is ready, a dialogue regarding the study will ensue. The study team member is responsible for guiding the discussion, and will be instructed to follow a standard format to ensure all required elements are introduced. Explanations will cover all aspects of participation requirements, participants' rights, and other relevant information. Individuals will have an opportunity to ask questions about the study and, if they choose to enroll, will sign a consent form. They will be provided with a copy of the consent form.

Study Procedures: General

This study includes three stages: (1) Focus Group, (2) In-lab Testing, (3) In-home Testing. Study procedures for only the in-home testing phase are delineated below for purposes of clinicaltrials.gov.

Study Procedures: In-home Testing Stage

Overview. A separate set of users (*N*=15) who did not participate in the in-lab activities will complete an in-home trial of a *FitSitt* prototype. The trial period will last between 3 and 7 days (depending on availability of prototypes and scheduling) and will capture free-living feasibility, acceptability, and potential health-relevant short-term benefits of the system. Participation will require two in-person contacts within approximately a 2-week period, which will include pre-session activities, an in-home orientation to *FitSitt*, and a follow-up visit in-home.

Pre-session activities. Participants will be mailed an activPAL and/or ActiGraph activity monitor package (including instructions and supplies) to don 3 days in advance of their initial in-home session. They will continue to wear these monitors for the duration of the chair trial period. This wear schedule will capture objective physical activity patterns prior to *FitSitt* availability, as well as activity patterns when the system is present in their home. Participants will also be sent electronic questionnaires (or hard copy if requested) to complete prior to their appointment. The battery of questionnaires (see Table 3) to be used at baseline include the same forms utilized in the in-lab session as well as an additional activity monitoring log [document "Activity Monitor Instructions Log" in iStar 21.2]. Any questionnaires left incomplete will be completed at the beginning of the in-home session.

In-home orientation. Participants will be provided with an in-home orientation to *FitSitt*. This session will be led by research personnel unaffiliated with Activ Sitting, Inc. Representatives of Activ Sitting, Inc. authorized to interact with participants may be present to help with device set-up and

installation as needed. The session will last approximately 2 hours. Personnel will use a checklist and data collection sheet to guide the visit and document necessary information [document "Tester Checklist Collect Home bsl" in iStar 21.2]. Included in this data collection form are a few open-ended questions as a mini-interview at baseline. This interview segment will be audio-recorded. The visit will generally address the following:

Daily activity engagement and environment: To aid in system placement, the research assistant will question users about their common daily activities and where they spend the most time sitting. (Responses will be documented.) Staff will recommend positioning the chair near this location, although users will make the final decision. The assistant will conduct a brief environmental scan to ensure the final location is safe and practical for the chair to be arranged. Final location details will be documented.

Hardware/software fitting: The research assistant will work with the participant to adjust the anthropometric settings (e.g., distance of treadles, seat depth). The assistant will also explain the use of the resistance settings so that users can choose the level of resistance best suited to them. For this study, resistance settings that allow only light physical activity will be demonstrated and recommended. Software setting options (e.g., frequency of cues to move) will be reviewed and set.

System features orientation, education, and interview: Users will be provided with an orientation to the *FitSitt* system prototype. The assistant will begin the conversation by engaging the participant in an evidence-informed dialogue about the effects of sedentary activity on health (e.g., cardiometabolic function) and daily life (e.g., sleep quality) and the benefits of disrupting prolonged immobile time across the day (Hwang et al., 2021; Saunders et al., 2020).

Participants' attention will then be directed to *FitSitt*. A discussion about how this seating system can act as a means of combatting long periods of inactivity will be had, linking it to the education on sedentary behavior. All available features of the seating system, their purpose, how to use them, and their potential benefits will be discussed and demonstrated. For instance, users will be shown the ergonomic design of the chair and how keeping one's feet on the treadles allows for maintenance of a non-slouched posture and expansion of the ribcage to support deeper breathing. The assistant will explain the purpose of the treadles, which are designed to allow for gentle mobilization (at light resistance settings), blood flow in the lower extremities, and leg strengthening (when higher resistance settings are activated). If a digital user interface displaying information is made available, participants will be oriented to that accessory and how to navigate it. Other features and functionalities such as a tabletop surface, rocking mechanism, and synchro-tilt recline will also be introduced, as they are available for the provided prototype. Individuals will also partake in a discussion of how the chair can be used during engagement in their personally relevant and meaningful activities (e.g., working on the computer, watching TV) with minimal disruption. Such activities may be practiced at that time. This is an important element of the educational session as the users should not feel discouraged from doing their traditionally sedentary activities that may have health and quality of life benefits (e.g., cognitive stimulation through reading and doing puzzles) (Copeland, 2019). Participants will be given a summary sheet of key discussion points [document "Sedentary Edu FitSitt Summary" in iStar 21.2).

Use expectations: The assistant will explain expectations for use of the chair during the study period. *FitSitt* will be presented as a tool useful for breaking up sitting without impeding desired activities—focus is not on its exerciser function but rather its capacity to reduce sedentary activity. Because we hypothesize that benefits will accrue at even low resistance settings, the assistant will encourage individuals to use the chair for brief, light activity with low resistance (as preset during fitting). The resistance setting follows empirical evidence supporting replacement of sedentary activity with light physical activity (Buman et al., 2010). Two types of evidence-based recommendations for treadle use will be offered to the user for which they can choose their most preferred: (1) when occupying the chair, pedal at their leisure across the day, with a goal of

interrupting 30-minute sitting periods with microbursts (1–3 minutes) of treadle use. Although no unified guidelines exist yet for reducing sedentary activity (Ryan et al., 2011), this dose is based on recommendations for persons with low-back pain (Atlas & Deyo, 2001) and is linked to reduced fatigue (Bergouignan et al., 2016), increased energy (Bergouignan et al., 2016), improved mood (Wennberg et al., 2016), and good metabolic health (Owen et al., 2010); or (2) pedal at their leisure across the day, with a goal of interrupting each hour of sitting with at least 5 minutes total of light movement. This second break length was informed by a Bond's study whereby disrupting each hour with a six-minute break was preferred over 3-minute breaks every 30 minutes and 12-minute breaks every 120 minutes in adults with overweight/obesity (Bond et al., 2014). Participants will also be encouraged to use the system as their primary seat, especially in instances where extended sitting is common such as while one works at a table/desk or during TV viewing. The assistant will further explain that although the more one accesses the treadle portion, the greater the energy expenditure, there is no expectation for continued use throughout the day; rather one should use the device at leisure and when comfortable and convenient to break up sedentary time. Participants will also be instructed to avoid using the treadles for more than one hour in total throughout the day to minimize any acute soreness potentially felt secondary to increased activity. Other features that promote movement such as the synchro-tilt recline to stretch the body and/or the rocking condition to engage core muscles will also be encouraged to use.

Safety considerations and device care: The research assistant will discuss safety considerations. Participants will be shown how to enter and exit the chair safely. If used in free-standing applications (e.g., TV watching in the living room) where the foot extension and/or tray may be in the line of travel, as opposed to stowed in front of a desk/table, the research assistant will educate the user about safe maneuvering around the system. Research staff will also discuss safety concerning any power cords attached to the system and secure cords (if necessary) in a safe manner (e.g., taping to floor). The prototype currently has a design for breakaway magnetic cords such that if the system is plugged in at that time and a cord is tripped on, the cord releases the magnet to reduce the tripping hazard. Device care, such as avoidance of having liquids placed/used near the electronic components of the system will be discussed.

Activity and sensor monitoring: Users will be asked to continue wearing the activity monitors they had donned prior to the home session throughout the duration of the *FitSitt* trial period. They will be given additional supplies in the event either monitor falls off prior to completion of the prototype trial period. Users will be provided with an activity monitor log [document "Activity Monitor Instructions Log" in iStar 21.2] to keep track of wear periods. Users will also be informed that the *FitSitt* has embedded sensors that track system usage (e.g., treadle movements, seat occupancy) in real time and may provide reminders (e.g., vibration from the seat surface) if the user has sat for too long based on a movement goal set during fitting. At this time, they will also be given the Biostrap EVO to wear on either wrist for the entirety of the in-home trial period. This monitor will not be provided in advance like in the case of the activPAL and ActiGraph activity monitors. Therefore, the wear period will only be up to 7 days instead of 10 days as with the activPAL/ActiGraph. Participants will be instructed to avoid baths, swimming, and saunas to protect all activity monitors.

Follow-up activities and equipment removal. After trialing the chair for 3 to 7 days, a follow-up visit will take place, which can occur in-person, virtually, or in hybrid format. (*FitSitt* equipment retrieval must be in person.) Self-report questionnaires (see Table 3) will be emailed in advance of the visit for completion. An audio-recorded semi-structured interview (see section 5.b.ii) to discuss the users' experiences during the study will be completed either virtually or in-person [document "Follow-up In-home Interview Guide" in iStar 21.2]. Research or Activ Sitting, Inc. staff will arrange to remove the chair and collect any other equipment (e.g., activity monitor) upon completion of follow-up activities.

Compensation

Participants will be compensated for their time to complete individual activities for the various stages of studies. Payment will be given by check mailed at the end of study participation and will be prorated based on activities they complete. The payment schedule for the in-home stage is delineated below in Table 2.

Table 2: Schedule of compensation/costs for each study stage

In-home Testing Stage (up to $165 total at end of study)
• $10 complete questionnaires at the beginning of the study • $20 wear an activity and health monitor for up to 10 days • $40 complete a 2-hour in-home orientation to *FitSitt* • $50 utilize a *FitSitt* prototype in home for 3 to 7 days • $10 complete questionnaires at the end of the study • $20 complete a follow-up interview • $15 return the loaned activity and health monitors

5.a.ii. Intervention details: *FitSitt* system

The *FitSitt* is a specialized wellness seating system [document "FitSitt Brochure" in iStar 40.1] to reduce and reverse negative outcomes of inactivity in older adults. The core chair provides seat-based stepping movement, full-body postural support that responds to and facilitates stepping actions, and reclining capabilities to allow stretching/postural changes, all of which are intended to be seamlessly integrated into individuals' daily routines and living spaces. The system will be enhanced using stakeholder feedback along the stages of development, adding specialized older adult-custom features that are tailored to older adults' expressed needs. To-date, no other fitness platform tailored to older consumers has been systematically developed and optimized to address sedentary activity in the aging population.

FitSitt reimagines the possibilities in sitting by reengineering sitting. [redacted]. One way we do this is by using sitting to induce and sustain healthy rather than slumped postures that characterize the seated positioning of many older people (Kuo et al., 2009). [redacted] Some key design and technical details are included below.

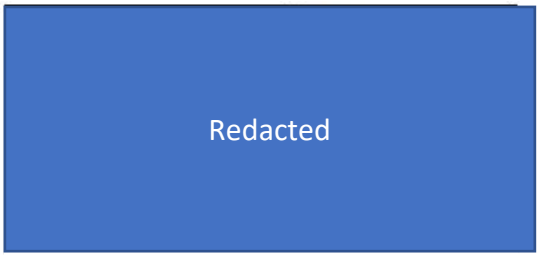

Figure 1. In-home Use of *FitSitt* for Free-standing or At-table Tasks.

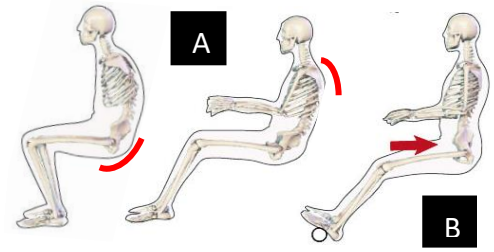

Figure 2. Juxtaposition of Typical Sitting Postures and Posture Supported

Such motions are easy to assimilate and do not require training—two considerations which increase physical activity engagement in older populations.

To operate the hardware, the user's

Redacted

Figure 3.

FitSitt Supports Behavior Change:

FitSitt will include a

Context-aware prompting to remind users to engage in physical activity is an effective intervention for older adults that facilitates long-term physical activity behavior change (Chase, 2013).

Figure 4. Potential *FitSitt* User Interface Displayed on an Attached Smart Device.

Importantly, FitSitt is classified as a general wellness device as opposed to a medical device regulated by the FDA, "offering general improvement to functions associated with a general state of health that do not make any reference to diseases or conditions." See the characteristics of a low-risk wellness device as noted in *General Wellness: Policy for Low Risk Devices* put forth by the FDA [document "General Wellness Device Regulations" in iStar 40.1].

5.a.iii. Participant suicidality information

Not applicable: information about self-harm or suicidality will not be collected as part of this study.

5.a.iv. Protect participant privacy and confidentiality

Confidentiality and participants' privacy will be maintained to the extent possible at each stage of the study. With respect to study personnel who will interact with participants, we will maintain strict standards that forbid the leakage of information about study participants to unauthorized individuals either within or outside the study team. Focus group and in-lab activities will be conducted in private spaces (if in person) that will be reserved for participants and research personnel. Although the in-home setting cannot be controlled by research personnel, we will ask participants to provide as private as possible of a space during the study activities. Audio and video recordings made during any stage of the study will be labeled based on participant ID as opposed to personally identifying information. Recorded content will be transcribed by authorized personnel. If personally identifying information was recorded during the session (aside from a person's likeness from video recordings), transcription files will be edited, redacting personal information from the file or replaced with a participant ID. Audio/video recordings will be listened to in a private setting and will be stored on a secure server available through USC until the transcription process and qualitative data analyses are complete. IDs and real names will only be connected through the REDCap secure data management system. Although audio-video recording will be required for participation in the various stages of the study, a media release form that specifies uses of such audio/video data beyond research purposes will be provided to participants for them to opt in or out of each use [document "Media Release Form" in iStar 40.1]. Combined, these strategies are likely to succeed in eliminating any possible harm to participants due to leaking of personal information.

5.a.v. Data management, storage, and monitoring plans

MPI Schepens Niemiec will oversee general data management and analytic functions with guidance from the USC team's statistician. Schepens Niemiec's team will collaborate with authorized *Activ Sitting, Inc.* and *Senseer Health Inc.* personnel regarding data management of sensor-captured data from *FitSitt* or any wearables linked to the system. *Activ Sitting* and *Senseer Health Inc*. will store, clean, and transfer raw usage data obtained from *FitSitt* sensors through secure cloud-based services (Linode Cloud Computing Platform [allowing HIPAA compliant storage and transfer] and SharePoint [protected through USC]. These data will be transferred to MPI Schepens Niemiec's team after initial formatting for secure storage on USC's protected network and shared drive.

To reduce the amount of artificial data captured from *FitSitt* during in-home trials, participants will be asked to reframe from allowing anyone else to use the system and to discourage animals from

sitting on the device. Additionally, participants will be queried during the follow-up interviews at home-based sessions about any instances that may have caused artificial usage readings.

Activity monitoring and physiological health data captured using ActivPAL, ActiGraph, and/or Biostrap, will be downloaded and cleaned upon return to the USC lab. Date-time stamps from the ActivPAL data, Biostrap data, ActiGraph data, and the *FitSitt* sensor data will allow correlation of activity and energy expenditure-related measures collected by the three systems. Questionnaires will be administered directly through REDCap database management system. REDCap is a secure, web-based application designed to support data capture for research studies, providing an intuitive interface for validated data entry. It also includes audit trails for tracking data manipulation and export procedures, automated export procedures for seamless data downloads to common statistical packages, and procedures for importing data from external sources. The REDCap website is password-protected and restricted to authorized users. All audio/video recordings will be transferred from the respective device from which they were recorded onto a password-protected, secure shared drive through the USC Chan Division; folders storing such data can only be accessed by authorized users. Any data collected in hard copy version that is not transferred to REDCap for electronic storage will be scanned in digital format to be stored on the aforementioned shared drive. The hard copies will be retained in a locked file cabinet in the USC Chan Division.

To minimize missing data, we will: (a) obtain alternate contact information for each participant at study entry; (b) employ one-on-one data collection when appropriate; (c) continuously monitor sensor output from *FitSitt* during in-home (remotely) and in-lab testing, (d) reschedule any missed data collection sessions, and (e) testers will receive regular refresher trainings across the study assessment periods to ensure they are adhering to all data collection guidelines. All study participants, including dropouts, will be described in terms of baseline characteristics. Reasons for missing data (e.g., activity monitor failure, participant hospitalization, participant withdrawal) will be documented to the extent possible.

Data monitoring will happen throughout the study. At the outset of the study implementation and at subsequent one to two-month intervals, Dr. Schepens Niemiec will conduct project staff meetings in which all study personnel who have contact with participants will discuss the safety and proper treatment of research participants. These meetings will be mandatory. This group will also assess participant recruitment, accrual and retention, data quality and timeliness, participant risk versus benefit, and the development of external conditions that could potentially affect the study. Significant problems or adverse events will be reported immediately to the USC IRB and summarized in a report to an NIA-approved safety officer (as described below). Study procedures that negatively affect participants will be halted if they present an immediate hazard to participants. Other protocol changes will not be made prior to IRB approval. Dr. Schepens Niemiec will discuss any issues that were identified as adverse events with research personnel at the subsequent project staff meeting to ensure that everyone is informed about events and potential protocol changes. She will also arrange for trainings as needed. If data and/or safety issues come to the attention of Dr. Schepens Niemiec between meetings, she will intercede as described above.

Data will also be monitored by a safety officer who is separate from the study and product development team. This person is a medical doctor, and is required and has been approved by the sponsoring funding agency (NIA). The study team must send compiled adverse event reports on a regular schedule (commensurate with the level of risk determined by the IRB) to this person for review. The team expects that semi-annual reports will be sufficient for this minimal risk study and will propose this to the safety officer upon approval from IRB. Dr. Schepens Niemiec will send a data and safety monitoring report to the safety officer upon conclusion of the study.

5.a.vi. Dissemination of findings

Study findings will be disseminated through various avenues. MPI Schepens Niemiec will lead dissemination to the academic community. She, or other members of the research team, will submit abstracts to and attend local, regional, and/or national scientific conferences to present findings in oral and/or poster format. Additionally, she will lead or oversee papers submitted to peer-reviewed scientific journals for publication. Because this funded study is a small business grant, much of the study findings will remain confidential to the business partner. All study findings will be presented in a way that protects the intellectual property belonging to Activ Sitting, Inc. Findings will also be reported in future grant submissions for additional research.

5.b. Instrumentation

Various instrumentation will be used for each stage of the study at different time points. Table 3 indicates at which stage and time point each measurement tool is utilized. Details about the tools are included in the subsequent sections. Information about the other stages of the study have been removed.

Table 3**:** Measurement tools and timing of implementation for the in-home stage of the study

Instrument	**In-home Test**
Standardized Questionnaires	
Brief Pain Inventory – Short Form	Pre; Post
Musculoskeletal Stiffness Questionnaire	Pre; Post
Brief Fatigue Inventory	Pre; Post
Physical Activity Scale for the Elderly (PASE)	Pre; Post
Self-efficacy for Exercise	Pre
Study-specific Tools	
Screening, Contact, Referral Form	Pre-consent
Background Questionnaire	Pre
Initial Impression of FitSitt	Post
Self-efficacy for Using FitSitt	Post
Activity Monitor Instructions Log	Throughout
Qualitative Tools	
Interview Guide – In-home	Post
Additional Tools	
activPAL	Throughout
ActiGraph GT9X-BT	Throughout
Notes: Pre = baseline; Pre-consent = prior to consent; Post = after intervention activities; Throughout = utilized/conducted during the entirety of a given session or study period	

5.b.i. Questionnaires/Survey Measures (names and citations)

- Standardized questionnaires
  - Brief Pain Inventory – Short Form (subscales: severity and pain interference): *Pain* will be assessed using two Brief Pain Inventory – Short Form subscales: severity and pain interference. The severity subscale measures amount of pain presently and at its "worst," "least," and "average" severity. The interference subscale assesses how much a person's pain disrupts everyday life. Both subscales are considered valid and reliable (de Andres Ares et al., 2015; Keller et al., 2004; Mendoza et al., 2006). The form takes approximately 5 minutes to complete. For eligibility purposes, if a person marks >8 on question #3, 5, 6, and 9c, these will be treated as red flags that will require follow-up to confirm eligibility.

- Musculoskeletal Stiffness Questionnaire: We will measure *stiffness* using the Musculoskeletal Stiffness Questionnaire (Halls et al., 2016; Watson et al., 2020), a 21-item form that takes ≤10 minutes to complete. This patient reported outcome measure has been used to assess overall joint stiffness as well as the physical and psychosocial impact of stiffness on everyday life in healthy adults across the lifespan (Watson et al., 2021). Studies include validation of the tool for persons with rheumatoid arthritis (Halls et al., 2016; Halls et al., 2018) and chikungunya disease (Watson et al., 2020). For eligibility purposes, if a person marks >8 on question #4 this will be treated as a red flag that will require follow-up to confirm eligibility.
- Brief Fatigue Inventory: *Fatigue* will be measured using the Brief Fatigue Inventory, a 9-item questionnaire that captures subjective report of fatigue severity. It takes approximately 5 minutes to complete. This tool demonstrates good psychometric properties and is sensitive to change (Mendoza et al., 1999). For eligibility purposes, if a person marks >8 on questions #1, 2, and 4c, these will be treated as red flags that will require follow-up to confirm eligibility.
- Physical Activity Scale for the Elderly (PASE): *Self-reported physical activity* will be measured via the PASE (Washburn et al., 1993). This 10-item instrument assesses physical activity commonly pursued by older adults, including leisure, household, and occupational tasks. The tool is a valid and reliable PA measure in older people (Washburn et al., 1999; Washburn et al., 1993) and takes roughly 5 minutes to complete.

o Study-specific questionnaires

- Screening, Contact, Referral Form: The screening form includes details for each of the three stages of the study (i.e., focus group, in-lab, in-home) and will be asked based on which stage we are recruiting for at the time. Questions are based on inclusion and exclusion criteria for each study stage. Additionally, important demographic details will be asked (i.e., age, sex, race/ethnicity, TV watching time) for purposes of recruiting a diverse sample of participants as required by the funding sponsors. This screening will be administered as a smart form such that select questions will only arise based on individuals' responses to previous questions and stages of study recruitment. The form includes a section for participant contact information as well as referral source.
- Background Questionnaire: Basic *demographic*, health-related, health behavior, and technology use data will be gathered using a study-specific questionnaire to characterize the sample. This questionnaire will be administered as a smart form such that questions will branch to additional questions based on responses from the individual. The form is expected to take approximately 5 minutes to complete.
- Initial Impressions of *FitSitt*: *Feasibility* and *acceptability* of *FitSitt* will be assessed using a study-specific questionnaire targeting users' cursory impressions of the system. Users are asked a variety of questions targeting issues ranging from perceived ability of the system to meet their health needs to the likelihood the system could be integrated into their daily lives. The form is expected to take approximately 3 minutes to complete.
- Self-Efficacy for Using *FitSitt* scale: *FitSitt use self-efficacy* will be assessed using a study-specific adaptation of the Self-Efficacy for Exercise scale (Resnick & Jenkins, 2000). Items have been modified to focus on using *FitSitt* as the mode of SA disruption rather than addressing exercise in general terms. The form is expected to take approximately 3 minutes to complete.
- Activity Monitor Log: This log was created to assist the research team in data analysis and interpretation of data collected from the activPAL/ActiGraph activity monitors. On this

form the user will document any instances of when the monitors fell or were taken off, wake/bed times, and any other comments they would like to include about monitor wear.

5.b.ii. Qualitative Instruments

- Interview Guide – In-home [embedded in document "Tester Checklist Collect Home bsl" and "Follow-up In-home Interview Guide"]: an audio/video-recorded semi-structured interview, informed in part by the Health Information Technology Usability Evaluation Model (Yen, 2010), will be conducted to evaluate users' experience, the training, and cursory impressions regarding the system's feasibility and acceptability. Individuals will be queried about such topics as potential efficacy to impact sedentary activity, physical activity, and health; perceived facilitators/barriers to adopting *FitSitt*; and suggestions for enhancement. Due to the semi-structured nature of the interviews, the interviewer may depart from questions included on the guide in order to probe for pertinent details and follow up on information disclosed by the participants.

5.b.iii. Additional Instruments

- activPAL Activity Monitor: The activPAL (Pal Technologies Ltd) activity monitor—a gold-standard accelerometer device for tracking seated and standing activities in free-living conditions (Grant et al., 2006)—will be placed on the user's thigh for comparison with data captured with *FitSitt* sensors and through video recording. The monitor is approximately 1.5 square inches and is lightweight. Additional information on the monitor is available here: https://www.palt.com/
- ActiGraph GT9X-BT: The ActiGraph GT9X-BT (ActiGraph, LLC) is a research-grade activity tracker within the family of ActiGraph monitoring technology considered to be gold-standard products for real-time assessment of movement. The device can be worn on multiple parts of the body ranging from the wrist to the ankle and has an option for showing activity feedback, which we will not activate for this study's purposes. Additional information about this device can be found here: https://theactigraph.com/actigraph-link. We intend to place the device on the user's lower body (ankle or attached to their shoe) as we hypothesize this will be the most likely location that will reliably capture the reciprocating movements required during *FitSitt* use.

5.c. Data Analysis

For the focus group, in-lab, and in-home testing phases of the study, procedures primarily include ones that are non-experimental or qualitative in nature, thus non-statistically driven data analyses will be conducted. These results are not reported in the clinicaltrials.gov and thus the analyses are not described here.

The various study stages will also include collection of a background/demographic profile comprised of factors such as *age*, *sex*, *race*, *ethnicity*, *other demographic characteristics*, *health-tracking habits*, and *household income*, and *access to in-home Wi-Fi*. Activity profile data will also be collected using self-report questionnaires addressing *physical activity level* and *self-efficacy to use FitSitt*. Activity and health monitor data (for in-lab and in-home stages) for assessment purposes will come from the research-grade activity monitor (ActivPAL and/or ActiGraph). Health and well-being indices include factors such as *ongoing health problems*, *health status*, *BMI (height and weight), pain severity, pain interference*, *fatigue,* and *stiffness*. Markers of acceptability of *FitSitt* are comprised of factors such as *initial impressions of FitSitt*, and address issues such as perceived engagement, and functionality. *FitSitt* usage data (for in-lab and in-home stages) will be obtained primarily from embedded sensors in the *FitSitt* system. Descriptive statistical analysis on all these variables will be generated for each sample and within key strata such as sex and age group (65–84, 85+) to characterize

the samples.

In-home testing data related to activity, physiological parameters, and *FitSitt* usage patterns will only include activity that takes place during waking hours, as determined by ActivPAL's (and/or ActiGraph's) proprietary algorithm and corroborated by participant activity monitor logs. We will capture and report descriptive statistics on factors such as: *sitting/lying behavior* (total duration sitting/lying per day, mean duration of individual sitting/lying bouts over the day, number of sitting/lying bouts per day, number of sit-to-stand transitions per day), and *activity level* (total sedentary time [ActivPAL/ActiGraph proprietary algorithm], total step counts per day, total stepping time per day). Objective *FitSitt* usage data will be aggregated to produce meaningful summaries of chair usage, such as: *seat occupancy* (total duration sitting in *FitSitt* per day, duration of *FitSitt* sitting bouts per day), *treadle usage* (duration of pedaling bouts per day, frequency of pedaling bouts per day, total time pedaling per day, mean speed during daily pedaling bouts), *synchro-tilt/recline usage* (number of times recliner is engaged per day, mean duration of recliner engagement per day). Additionally, *pain, fatigue, stiffness,* and *physical activity/sedentary activity behaviors* (self-reported and objective) will be collected both pre-use of the system and at the conclusion of the study. Pre-post scores will be compared, for exploratory purposes, using a paired samples *t*-test (or Wilcoxon signed-rank test) to indicate changes, if any, after having *FitSitt* in the home for a short time. Additionally, we will explore the association of *FitSitt* adherence (minutes of treadle usage dichotomized at the median) to confidence to use *FitSitt* using Spearman correlation. Normalizing transformations will be applied to variables as appropriate; sparse data may be recoded to dichotomous or ordinal data.

Power Analysis

The purpose of this study is to continue *FitSitt* development, and to test the feasibility of study procedures that would be used in a larger study investigating the efficacy of the system to decrease sedentariness in older adults. Accordingly, power calculations are not appropriate. However, sample sizes chosen for each stage of testing are justifiable based on previous research. Iterative product development requires only small samples—5 to 20 users per prototype iteration (Faulkner, 2003)—justifying our modest sample sizes of N=15–30. The additional participants beyond the high end of the recommended range will increase chances of identifying lower-level usability issues (Faulkner, 2003; Virzi, 1992). The data from this pilot study will elicit rich information for a properly powered, more in-depth study in Phase II.

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