Study Protocol & Statistical Analysis Plan

NCT Number: NCT05080426

June 10, 2024

Written Description of the Clinical Study (including objectives, design, and methods)

Key Objectives: Our key technology objectives are: 1) develop intervention implementation support products to enhance usability and adoption; 2) develop an eLearning management system to enhance user engagement and delivery processes including automation of feedback reports to motivate behavior change and enhance change sustainability; 3) develop a new Supervisor Support for Family Care and Sick Leave Use Module augmenting the core FSST program (designed to increase overall family supportive supervisor behaviors) to also increase targeted support for the use of family care and personal sick time leaves, which many workers face difficulties accessing without fear of job penalties; 4) test and evaluate FSST 2.0 for commercialization readiness.

Design & Methods:

Organizational Settings

Data were collected via surveys of managers and their direct reports from two universities in the U.S.: a medical university located in the Southwest region (referred to as university 1) and a public university located in the Midwest region (university 2). University 1 focuses on cancer treatment, conducts clinical trials, and trains students in their School of Health Professions. In total, approximately 5,000 trainees participate in university 1 educational programs each year, including clinical residents and fellows, nursing trainees, research trainees, student program participants, and interns. This organization employs approximately 22,000 individuals, including over 1,700 faculty members. University 2 is a unionized, public institution with over 15,000 students that employs over 500 faculty and 1,000 staff members.

Data were collected from both managers (defined as anyone in a supervisory role in a formal capacity – i.e., someone with direct reports) and their direct reports (referred to as employees) over the course of approximately 5 months (see Figure 1 for a timeline of research). For both universities, participants completed a baseline survey and two follow-up surveys approximately 3 and 5 months after the baseline survey (referred to as Times 1, 2, and 3

Participants, Recruitment, and Survey Procedures

An overview of the timeline of the study can be seen in Figure 2. Each organization designated a primary point of contact for the research team. This individual developed a list of all managers and employees who would be invited to participate in the study and helped facilitate recruitment. Each point of contact provided invitees' names, work email addresses, role designations (i.e., manager or employee), and identified each invitee's manager to allow for linking in subsequent data analyses. These details were uploaded into a customized online learning management system (LMS), which is a software application that has the capability to automate the delivery and tracking of educational programs, such as the training in the current study. This LMS system sent out recruitment emails to managers and employees that provided participants a link to complete online surveys and (for managers) participate in training activities.

The contact at university 1 randomly selected 368 managers from the total pool of managers who completed one or more of the organization's leadership development programs, which are designed to teach foundational leadership skills and behaviors. For those managers with 12 or fewer direct reports, all direct reports were invited to participate in the study. For all other managers (i.e., those with 12+ direct reports), 12 direct reports were randomly chosen and

invited to participate. This resulted in a total of 1,899 employees being invited to participate at university 1. The contact at university 2 provided a list of names and emails for all academic managers at the university and their direct reports (136 managers and 811 employees). Non-academic managers were excluded from the study per the university's determination.
At both universities, a leader at the organization (i.e., the Associate Vice President of the Leadership Institute at university 1 and the Provost at university 2) sent an email to all potential participants one week prior to data collection describing the purpose of the study and notifying participants to expect recruitment emails from the research team via the LMS system. Potential participants were sent four recruitment emails for the Time 1 survey over the course of approximately one month.

After Time 1 recruitment, the intervention training became available for managers at university 1 (described below). These managers were sent five recruitment emails about the training over the course of approximately one month. Additional reminders about behavior tracking were sent to those managers who had completed both training modules shortly after the training closed. After the training closed, all managers invited to participate in the baseline survey at university 1 were sent an email by the Leadership Institute inviting them to participate in a webinar, approximately one month after the training closed.

Following the webinar, managers and employees at both universities were invited to participate in Time 2 and Time 3 surveys, which fell approximately 3 and 5 months after Time 1 survey. Prior to each survey, the same leader who had previously announced the study at each university emailed all invitees to announce the follow-up surveys and share that invitations from [masked company name] would follow. Participants received three reminders about the Time 2 survey and four reminders about the Time 3 survey. Managers at university 2 (the control group) were offered the intervention at the conclusion of the study.

The intervention included multiple components for managers: two online training modules (created by [company name masked for review]), a 10-day online behavior tracking exercise, and an online webinar. The online training and behavior tracking components were implemented through an LMS created by [company name masked for review], in coordination with [company name masked for review].

The first online training module was developed by [masked company name] in coordination with [masked company name], based on previously studied interventions (e.g., Kossek, Hammer, Kelly, & Moen, 2014). The module, titled *Supportive Supervision and Management for Family and Personal Life*, focused on work-life and family-supportive supervisor behaviors more broadly, including examples of work-life conflict and its implications, the importance of family-supportive supervisor behaviors for employees and organizations, and types of family and personal support, including emotional support, job and personal problem-solving support, creative work-family management, and role modeling. The content also covered performance support behaviors, including measurement and direction, feedback and coaching, providing resources, and support for change. Similar content and interventions have been found in previous research to benefit employees' safety and other behaviors at work (e.g., Hammer et al., 2016), as well as outcomes like job performance, organizational commitment, engagement, job satisfaction, and turnover intentions (Odle-Dusseau, Hammer, Crain, & Bodner, 2016).

The second online training module was developed by [masked company name] and the eLearning instructional designers at the [masked company name] utilizing content unique to this study. Titled *Leaders and Leaves: Supporting Employee Use of Paid Family and Sick Leave*

Policies, this module focused on increasing supervisor support for paid family care and sick leave use. More specifically, this training focused on developing work-life leadership skills by helping managers learn to increase employees' awareness of the availability of paid family and sick leave policies and introducing other behaviors managers could enact to support use of paid family and sick leave policies with the ultimate goal of increasing the effectiveness of existing paid family and sick leave policies. Behaviors focused on listening and emotional support, education and policy access, reassurance and minimization of negative perceptions, organizing work to support leaves in ways that benefit both the organization and the employee, enhancing employee experiences of leave, and role modeling.

Each module took approximately 30 minutes to complete, included both active listening and participation components (e.g., matching activities; quizzes), and provided multiple examples of situations managers may encounter in their work, coupled with examples of supportive strategies to utilize in each situation. After completion of the online training, managers were asked to track the number of supportive behaviors they engaged in across 10 work days as a way to practice and implement the materials discussed in the online training. Managers were asked to set goals in the LMS for the number of family and personal support behaviors, performance support behaviors, and leave use support behaviors they would enact over the 10-day period. Managers were encouraged to set goals that totaled one to two times the number of direct reports they supervised (e.g., if a manager supervised 10 employees, they were encouraged to set goals of 10-20 instances of support behavior over the 10 work days they selected for tracking). Managers received reminders on each of the 10 days they selected for tracking; reminders included links to the behavior tracking section of the LMS to provide an opportunity to easily track the number of behaviors enacted each day.

Finally, managers were invited via email to attend one of two virtual webinars led by the co-founders of [masked company name]. The webinars contained the same content but were offered on different dates and times for participant convenience. All managers were invited to participate, regardless of whether they completed the online training. Each virtual, one-hour webinar reiterated the main points from the online training and allowed for a discussion among managers related to course content, including sharing their own insights/personal experiences and asking questions about course materials. See Figure 1 for participation numbers for the intervention components. At university 1 (i.e., the intervention organization), a total of 174 (47% of recruited managers) completed at least one component of the training.

Figure 1. Timeline of research design and data collection at intervention and control sites.

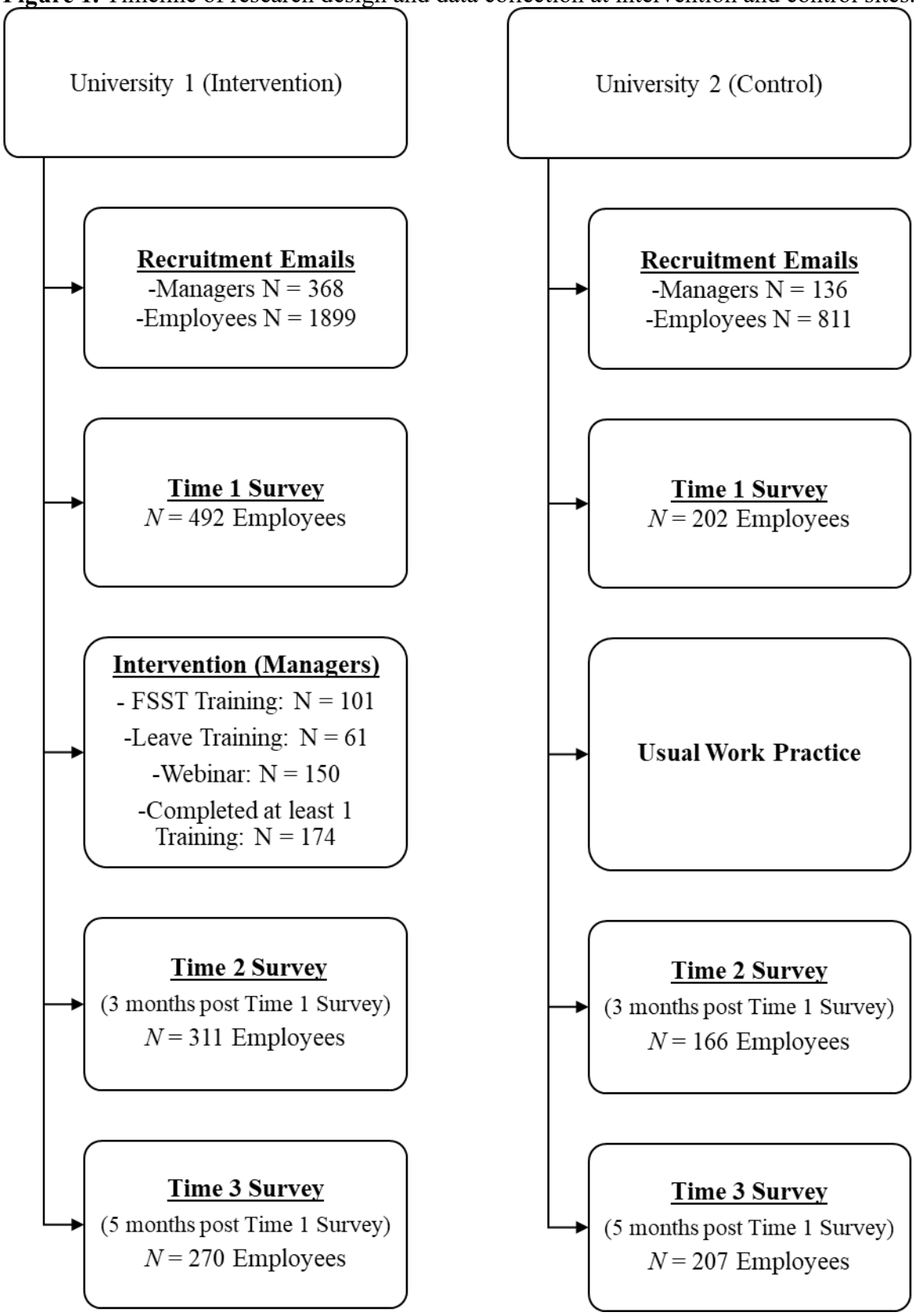
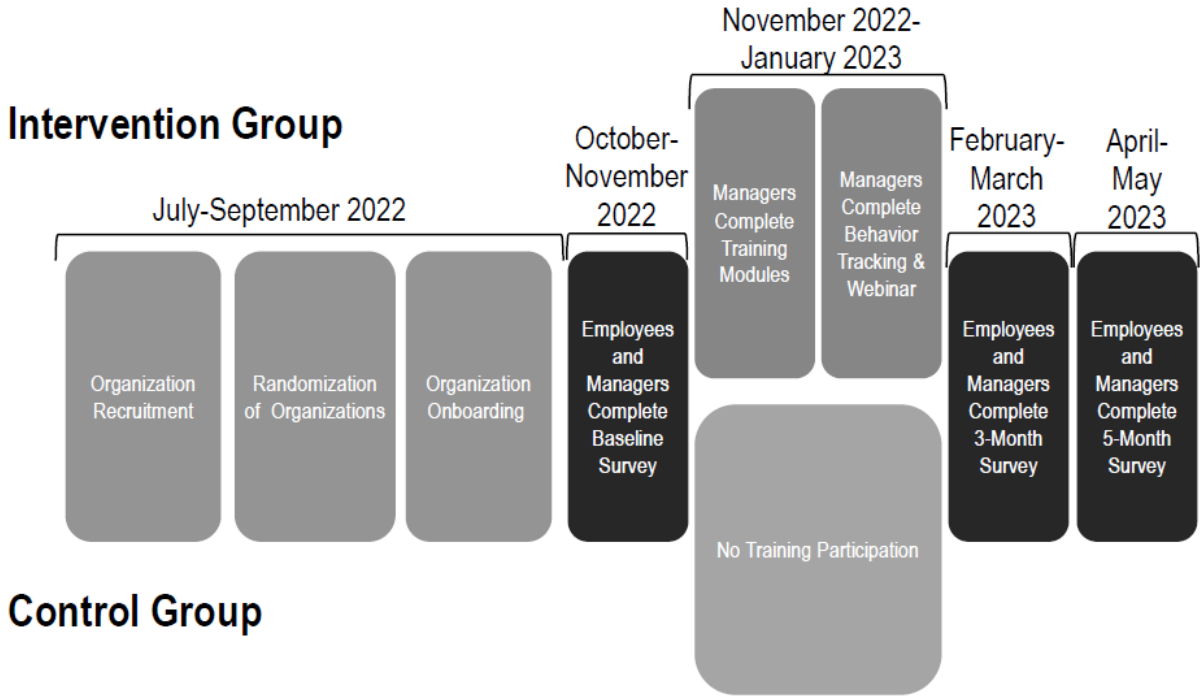


Figure 2. Timeline of research design and data collection at intervention and control sites.



Data Analysis: The scores of embedded quizzes will be analyzed using paired t-tests to test the improvement in the supervisors' learning. The pre- and post-training Workplace Assessment data will be coded and entered using IBM® SPSS ® Statistics software for analysis. Descriptive statistics (means, frequency counts) will be used to ensure that the data are within pre-specified valid ranges defined for each variable. Internal consistency reliability analyses will be conducted on all Likert-type measures. Descriptive statistics (means, frequency counts, percentages) will be used to describe the sample, and the aggregated means of family-supportive supervisor behaviors and employee outcome variables. The data will be generated from a clustered-design with all participating employees within participating supervisors and employers at two time-points. Given the clustered nature of the data, standard general linear and generalized linear mixed model approaches for clustered designs (i.e., hierarchical linear models, multilevel models; Murray, 1998; Murray, Varnell, & Blitstein, 2004) will be used for the analyses to detect changes between pre- and post-training, and to detect group differences (e.g., Condition A vs. Condition B; employees with vs. without eldercare responsibilities) in the relationships between supervisors' family-supportive behaviors and employee outcomes. Focus group transcripts will be entered into ATLAS.ti, a qualitative software program for data analysis. ATLAS.ti is a powerful tool for analyzing textual data. Using the coding functions of the program, we will analyze the transcripts to identify common themes around the perceived usefulness of the program using open coding procedures. We will then assess the associations among these themes and categories using axial coding procedures (Stauss & Corbin, 1998).