



Investigating the efficacy of a self-directed parenting intervention to reduce risky behaviors among college students: Study protocol for a multi-arm hybrid type 2 randomized control trial

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ABSTRACT

Background: Early adulthood is a critical developmental period when many youth transition from living at home to the relative autonomy of college. This transition results in increased opportunity for positive growth and identity development – and for risky substance use and sexual behaviors. Parents continue to influence young adult behavior even from a distance; however, few studies have rigorously tested parent-college student interventions.

Methods: This multi-arm hybrid type 2 trial tests the short- and long-term efficacy of a self-directed handbook for parents of first-year college students. In the summer before college, parent-student dyads are randomly assigned to one of three conditions: control, Parent Handbook, or Parent Handbook Plus. Handbook parents receive encouragement via phone calls to read the handbook and complete activities with their student before leaving for college. Handbook Plus parents also receive booster messages targeted at risky or stressful times. Participants complete surveys of intervention-targeted knowledge, attitudes, and behaviors at baseline and four months after baseline. Students complete three additional surveys at nine, 16, and 21 months after baseline. Dyads in the intervention conditions also reported on handbook utilization, perceived usefulness, and engagement with intervention materials.

Discussion: Self-directed family interventions may be a feasible strategy for involving parents of college students. This trial aimed to determine: 1) the efficacy of a self-directed handbook intervention for parents of first-year college students, including whether the addition of periodic booster messages enhanced efficacy; and 2) how variations in handbook utilization, perceived usefulness, and engagement were linked to student outcomes.

1. Introduction

First-year college students who transition from home to campus living are at increased risk of harm due to substance use and other risk behaviors, especially during their first six weeks of college [1,2]. Rates of binge drinking [3], marijuana use [4,5], and nonmedical use of prescription medications have increased among college students more than among their non-college peers [6–9], a pattern especially true for marijuana use [10,11]. Young adults also increase HIV sex-

risk behaviors during this transition, including inconsistent condom use and multiple sex partners [12–14]. Consequences of these behaviors can be substantial and life altering, and have a significant negative societal impact [15–18].

Parents are influential but underutilized during this transition. Clear, consistent parental communication is protective and helps college students develop healthy autonomy [19–26]. However, few studies have tested parent-college student preventive interventions, and

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none, to our knowledge, has tested the efficacy of specific implementation strategies.

Engaging, interactive interventions are more effective than didactic interventions [27], but group-administered formats that facilitate conversation, role play, and coaching are logistically difficult for families during the transition to college. As an alternative, self-administered family interventions have higher participation rates, particularly for families who might be harder to reach [28,29], and are equally effective (and in some cases more so) as in-person delivery, particularly when the intervention promotes interaction and conversation [30–32]. This research indicates that utilization of, perceived usefulness of, and active participation with the intervention materials are critical to program success [33–36].

One existing parent handbook intervention reduces alcohol use among first-year students [37,38]. However, the handbook is solely didactic, and effect sizes are mostly quite small [39]. We know little about specific mechanisms by which parent-college student preventive interventions are effective, and whether implementation strategies can enhance their efficacy. Therefore, this study employs a multi-arm hybrid type 2 randomized control trial design.

1.1. Study aims & hypotheses

This study addresses two aims. First, it tests the efficacy of a handbook intervention for parents of students transitioning to college. We hypothesize that students in the Handbook and Handbook Plus conditions will (a) engage in fewer risk behaviors, including initiation, use, and abuse of substances (alcohol, marijuana, opiates, and prescription stimulants) and HIV/sex risk behaviors; and (b) report fewer physical, emotional, social, and academic harms in comparison to students in the control condition.

The second aim is to test mediational pathways between utilization, perceived usefulness, and engagement with handbook materials and expected intervention changes in student risk behaviors and associated harms. Further, we will determine whether booster messages enhance the efficacy of the intervention by comparing outcomes in the Handbook vs. Handbook Plus conditions. We hypothesize that the effect of the intervention on student risk behaviors will be mediated by engagement in and use of the handbook. Relatedly, we expect that parents in the Handbook Plus condition will engage more frequently with handbook content and in conversations with their student. As such, we expect that intervention effects will be more pronounced for students whose parents are enrolled in the Handbook Plus condition.

2. Methods

2.1. Study design

This study's design is a multi-arm hybrid type 2 randomized trial aimed at simultaneously testing the short- and long-term efficacy of a self-directed handbook for parents/caregivers of first-year college students, and the role of the implementation strategies described in the intervention delivery section below. Although throughout the remaining sections of the paper we refer to "parents" and "parent-student" dyads for simplicity, please note that the study was not restricted to parents only; other adult caregivers could also participate. In order to obtain the sample size needed to detect intervention effects within the yearly grant budget, we had to enroll participants in two consecutive cohorts across two years. In the spring/summer before college, parent-student dyads were randomly assigned to one of three conditions: control, Parent Handbook, or Parent Handbook Plus. Cohort 1 parent-student dyads were recruited in the spring/summer of 2017 and Cohort 2 parent-student dyads were recruited the following spring/summer, in 2018. Washington State University Internal Review Board ap-

proved the study design and procedures, and informed consent was obtained for all participants.

All parents and students were surveyed at baseline prior to students entering college (and prior to receiving the handbook for those in the intervention conditions) and again about four months after baseline during late fall of the student's first semester of college. Handbook Plus parents were also surveyed briefly about their experience with the booster text messages following the final booster message. The students (but not parents) were surveyed three additional times – at nine months (spring of first year), 16 months (fall of second year), and 21 months (spring of second year) after baseline. Surveys were designed to collect information on intervention-targeted parent and student knowledge, attitudes, and behaviors. Students and parents in the intervention conditions were also asked to report on handbook utilization, perceived usefulness of the handbook, and active engagement with intervention materials.

2.2. Study setting

This study takes place at a large public research university in the Pacific Northwest. Current undergraduate student enrollment is approximately 26,098; 53% are female and 32% are from an under-represented minority.

2.3. Randomization

For each cohort, we used a computer-generated sequence to randomly identify a sample of students from the full group of admitted students who (a) indicated they were planning on enrolling for the subsequent academic year, and (b) were younger than 21 years old. After completing enrollment in Cohort 1, we assessed balance across conditions and found imbalances in gender and ethnicity across conditions. We stratified and tracked recruitment in Cohort 2 to address that imbalance. We randomly assigned students (and their parents) to one of the three conditions, again using a randomly generated sequence. Student-parent dyads were recruited into their assigned conditions.

2.4. Study participants

Student-parent dyads were excluded if: a) one or both refused to participate, b) one or both did not speak English, c) the student lived off campus, d) the student did not enroll in classes by the tenth day of the first semester, and/or e) one or both did not complete the baseline survey by the end of July before beginning college. For students in two-parent families, parents were instructed to decide which parent would complete the study surveys. Our target sample size was 900 parent-student dyads (300 per condition) across the two cohorts. Dyads were recruited and assigned as follows: control (N = 309), Parent Handbook (N = 285), and Parent Handbook Plus (N = 325) (see CONSORT diagram, Fig. 1). Across conditions, students were an average of 18 years old at entry to college, 56% were male, and 39.8% were non-White.

2.5. Intervention: the parent handbook

First Years Away from Home: Letting Go and Staying Connected is a theoretically guided, developmentally targeted, and self-directed handbook intervention for parents of students transitioning to college. The handbook was designed to reduce risk and enhance protective factors by helping parents: 1) understand the developmental and situational challenges their student will confront as they transition to college; 2) clarify and discuss their expectations for their student's substance use, sex risk, and academic behaviors while at college; and 3) help their student (a) clarify their values and norms regarding their

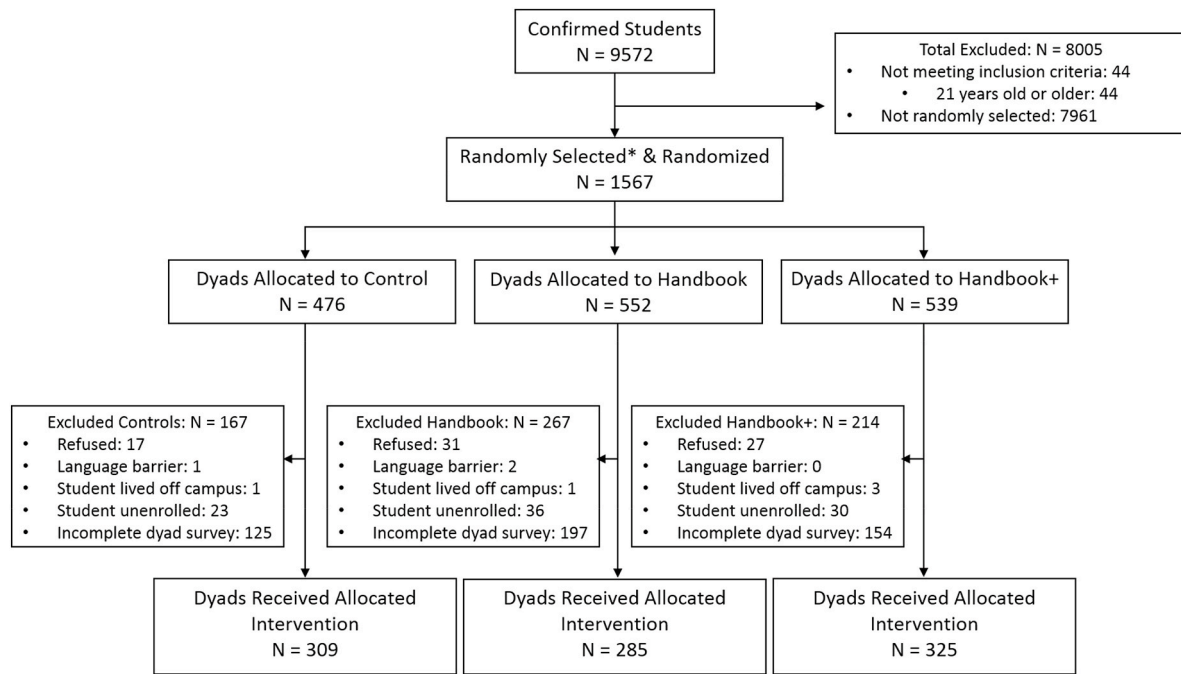


Fig. 1. CONSORT diagram describing participant randomization to condition, allocation of the intervention, and exclusion reasons.

academic, sexual, and substance use behaviors, and (b) develop autonomy, self-regulation, and decision-making skills. The content draws from two developmental theories, both with strong empirical support, to model parent-student interactions and how they may affect risk and protective factors at this transition to college (Fig. 2). The Social Development Model [40] emphasizes the social-context drivers of behavior, while Self-Determination Theory emphasizes the internal drivers of behavior [41]. Both theories have been used extensively to describe the mechanisms that link parenting and family dynamics to the development of positive and problem behaviors from early childhood through young adulthood [42–44], and both theories emphasize the importance of parenting practices as a primary protective factor in child development.

The 16-page handbook developed for this study includes modules adapted from the *Raising Healthy Children Navigating Independence* program, developed at the University of Washington's Social Development Research Group as a handbook for students transitioning out of

high school. These modules were a part of a comprehensive school- and family-based program to impact healthy development and reduce drug use [45]. We expanded and adapted these modules to include specific guidance for parents of first-year college students. The handbook packet was designed to be completed in the two months before students begin university and then to be referred to as needed throughout the student's college career. The packet includes the handbook itself, cards for interactive parent-student activities, worksheets, and checklists to guide completion of the handbook activities.

The handbook is divided into four sections: 1) the young adult brain, 2) values and committed actions, 3) how parents help their student, and 4) parent role scenarios. In the last two sections, the handbook describes three parent roles, each corresponding to one of the three parenting constructs in the theoretical model (Fig. 2): family management (referred to in the handbook as “Safety Monitor”), autonomy support (“Coach”), and emotional support (“Cheerleader”). Throughout the handbook, there are also questions for parents to

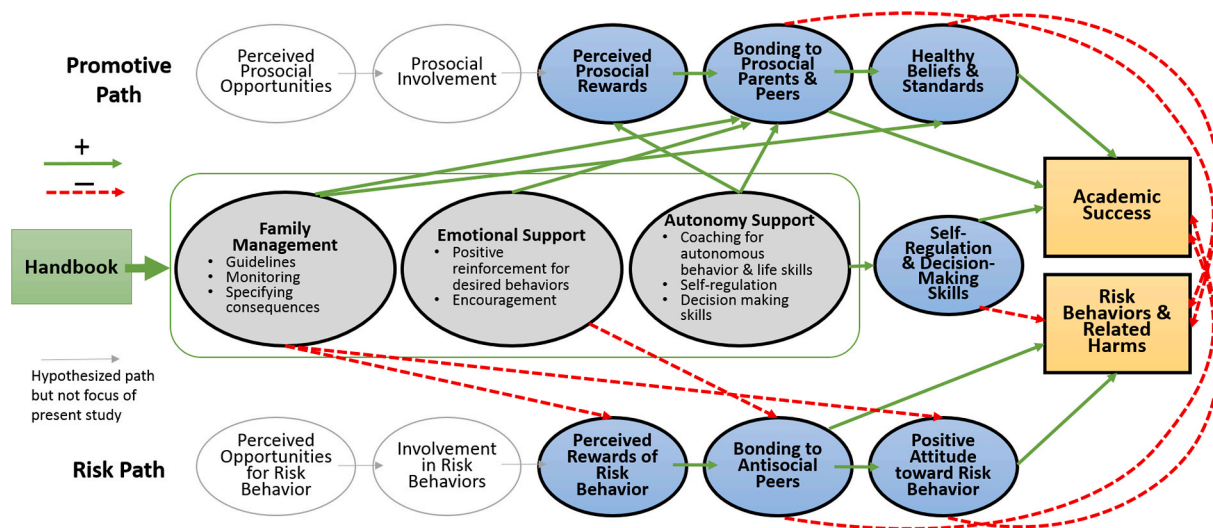


Fig. 2. Theoretical model for the First Years Away from Home Study.

think about, interesting facts and research findings, conversation starters, activities for students to do on their own, and activities for parents to do on their own or with their student to practice behaviors and communication strategies that characterize each of the parenting roles.

2.6. Intervention delivery

The *First Years Away from Home: Letting Go and Staying Connected* intervention packet was mailed to parents in the two intervention conditions (Parent Handbook and Parent Handbook Plus) in June prior to the start of the student's first semester in college. These families were asked to complete the handbook at their own pace by mid-August before the students' move to campus. Our goal was that families would read through the handbook and complete at least four activities in each of the two-week periods between check-in phone calls from Prevention Science graduate students trained as Transition Support Specialists. We estimated that it would take families 8 h or less to complete the entire handbook. To facilitate conversations with parents about the handbook, Transition Support Specialists received 8 h of training from one of the investigators and our senior family outreach supervisor approximately one month before the handbooks were mailed to families. The training provided information about the handbook and their role as Transition Support Specialists, as well as training and opportunities to practice using motivational interviewing. After completing at least three practice calls with the research team and being approved by the senior family outreach supervisor, each Transition Support Specialist was assigned an average of 48 families. Specialists were tasked with contacting intervention parents by phone, email, and/or text messages periodically between June and August. In addition to introducing the handbook, they also sought to: 1) motivate parents to complete the handbook activities before students left for college and help them apply the material to their families; 2) troubleshoot problems and issues as they arose; and 3) gather and record information about the families' participation in and experiences with the handbook. Transition Support Specialists were supervised in 1-h weekly group meetings with the senior family outreach supervisor throughout the primary intervention period.

Starting after the primary intervention period, parents in the Handbook Plus condition also received periodic booster messages, tailored to each family through use of their child's name, via text message or email (depending on the parent's preference) to provide tips for communicating with their student and to remind them of handbook content that might be useful throughout the student's first year. As an introduction to this aspect of the study, the first message was sent the week before the semester starts. This message stated:

"Welcome to the [university name] family! The First Years Away from Home study wants to remind you that the Parent Handbook you received this summer is a great resource. This year we will be sending helpful tips for how to best support [student name] during [his/her] transition. Each message will remind you of the three important roles you play: Coach, Cheerleader, and Safety Monitor. Best of luck with the upcoming move!"

During the first semester, a message was sent once a week for the first six weeks and then approximately every 10 days for the rest of the semester. During the second semester, a message was sent approximately once a month. The timing and content of these messages are strategically targeted based on common campus (e.g., football games), academic (e.g., finals week), or student life (e.g., Mom's Weekend) activities. Each message also highlights a specific parent role (i.e., Coach, Cheerleader, or Safety Monitor), and some messages reference specific content from the handbook.

Consistent with previous research on self-directed handbook interventions in college populations [46–48], we used a "business as usual" control condition because it was an ecologically valid compari-

son. Therefore, other than the information and opportunities provided to all parents during the university's parent/student orientation program to learn about ways to support their students, parents and students assigned to the control condition did not receive additional materials from this study.

2.7. Study procedures & data collection

The recruitment period was from March to May during students' high school senior year. A link to the online baseline survey was emailed, mailed, and/or texted to parents and students once both family members agreed to participate. Participant recruitment had to be completed by May in order to allow enough time for intervention participants to receive and complete the handbook intervention prior to students' August matriculation into college. Therefore, we oversampled for each condition. Intervention participants received the handbook via postal service in mid-June, about two months before students moved to college. Students and parents also complete online surveys in late fall of their first year (four months after baseline) of college, and students (but not parents) complete further surveys at nine months, 16 months, and 21 months after baseline. Participants had a six-week window in which to complete the baseline survey and four weeks to complete the fall/spring surveys, with several prompts/reminders via phone, email, and/or postal mail. A brief survey was also sent to the Handbook Plus parents at the end of their students' first year of college (following the final booster message) to assess their experiences with the booster messages they received throughout that year.

We had a specific window of time in which recruitment/enrollment in the study had to occur since the intervention (i.e., Handbook materials) had to be sent by mid-June in order to allow enough time for parents/students to complete it prior to the student leaving for college in mid-August. Therefore, we oversampled for each condition.

2.8. Primary outcome measure

The primary outcome for this study was change over time in 30-day alcohol use. Specifically, the study examined the impact of the two intervention conditions on changes in student 30-day alcohol use from baseline to four months, nine months, 16 months, and 21 months after baseline. The 30-day measure is a standard validated measure used widely to study adolescent/young adult substance use [49]. Students were asked: "During the past 30 days, on how many occasions have you used alcohol?". They responded on a 7-point rating scale ranging from 0 occasions to 40 or more occasions.

2.9. Secondary outcome measures

In alignment with our theoretical model (Fig. 2), secondary outcomes for this study included measures of academic success and student conduct sanctions as well as sexual and substance use risk behaviors and their related harms and consequences. The academic measures, which were collected through university administrative data at the end of each semester for students' first two years in college, include cumulative grade point average and continuous matriculation at the university. Student conduct measures will include whether a student has ever been sanctioned for a conduct violation and repeat offenses.

Changes in risk behaviors and their related harms and consequences were measured from baseline to four months, nine months, 16 months, and 21 months after baseline. The risk behaviors included validated measures of lifetime and past 30-day frequency of: risky sexual behavior, alcohol use, marijuana use, prescription drug misuse, and illicit drug use. We also examined past two-week heavy episodic drinking by asking students how frequently in the past two weeks he/

she has had more than four (for females) or five (for males) drinks of alcohol in one sitting, and severe binge drinking of eight or more (for females) or 10 or more (for males) drinks in one sitting in the past month.

The risk behavior harms and consequences were measured by using three validated scales: the Rutgers Alcohol Problem Index [50], The Marijuana Consequences Index [51], and the Sexual Consequences Index [52]. Each scale asked students to report how frequently they have experienced any of a list of specific consequences related to the specified risk behavior (alcohol use, marijuana use, or sexual activities) over the past month.

2.10. Mediator measures: responsiveness to intervention

To address Aim 2 of the study, parents in the intervention conditions were also asked to report on their responsiveness to the intervention. Specifically, we assessed handbook utilization, perceived usefulness of the handbook, active engagement with intervention materials, and the usefulness of the Transition Support Specialist calls during the second parent survey four months past baseline. These items were developed specifically for this study to assess theoretically meaningful aspects of participant responsiveness to the handbook intervention. Handbook utilization was measured through parents' reports of the total amount of time spent reading the handbook, number of total sections read, number of total activities completed, as well as how frequently families read, reviewed, consulted, or referred to topics in the handbook after the student moved to college. Perceived usefulness was measured by parents' reports on several items regarding how useful the handbook and its various components (e.g., activities and conversations) were in preparing them and their student for the transition to college, providing information they did not already know, helping parents discuss important topics with their student, giving them information and/or strategies to use in their relationship with their student, as well as whether parents would recommend the handbook to other parents of first year college students. Active engagement with the intervention materials was measured by parents' report of how engaged their student was during handbook activities and conversations, and how parents would characterize their continued use of the handbook. Response options included: 1) To refresh my memory about a topic, 2) To problem-solve an issue that came up between {student name} and me, 3) To prepare for a conversation with {student name}, and 4) Other reason (please specify). In addition to these items, parents in the Handbook Plus condition were also asked to report on the usefulness of and engagement with the booster text/email reminder messages. More specifically, parents reported how often they read the text/email reminders, how often the text/email reminders resulted in them reading, reviewing, or consulting the handbook, how often the text/email reminders resulted in them contacting their student, and how useful the text/email reminders were in helping them communicate with their student.

2.11. Statistical analyses

To address the first study aim of determining intervention impact on change across time, we will model latent growth curves for each of the hypothesized outcomes. This approach is similar to hierarchical linear regression where repeated measures within individuals are modeled as random effects. This is accomplished in a structural equation framework in which two factors are estimated. The first is fixed to be equal to the baseline measure of the outcome. The second factor is a latent construct on which each of the repeated measures load based on the interval between measures. As a latent construct this factor has a mean which is equivalent to the average rate of change (slope). In the usual fashion, we specify a two-factor model: an intercept factor set to baseline levels, and a linear slope factor estimated

with factor loadings set to indicate non-equal intervals between surveys. A covariance is typically estimated between the intercept and slope factors to control for effects of baseline levels of the outcome on the rate of change (slope) of the outcome. A non-linear slope will be estimated using quadratic forms for loadings on the slope factor; however, we expect primarily linear increases over all five time points. Control variables will be added in the next step. Our planned control variables include: student's age, race, gender, study cohort, high school GPA, and first generation college student status. For analyses of substance use outcomes, we will also include substance use at baseline (before college). Finally, intervention group assignment (in the form of two dummy variables) will be added as predictors of the mean and variance of the slope factor; random assignment should preclude group effects on the intercept set at baseline. We expect these parameters to reflect significant positive slope means and variances in the unconditional model and the minimally conditional model. In the final models, intervention dummy variables are hypothesized to have significant negative effects on slope mean and variance compared to the control condition indicating that both intervention conditions reduced the rate of escalation in risk behaviors and consequences and also reduced the variability in these outcomes. By manipulating the coding of dummy variables we can then test the comparison between Handbook and Handbook Plus with the expectation that Handbook Plus parameters will be significantly stronger in the expected direction than those for Handbook participants.

To address the secondary study aims, data collected from parents and students in the two intervention conditions will be analyzed. Preliminary intent-to-treat analyses will be conducted via ANCOVA on the mediators (measures of intervention responsiveness) at post-test (i.e., four months after baseline) to determine if handbook responsiveness is higher in the Handbook Plus condition compared to Handbook. It is not expected that responsiveness measured at post-test will differ by condition because the post-test survey was completed early in the booster text message phase of the Handbook Plus intervention. Next, latent growth curve analyses described above will be extended to include mediating variables measured at post-test (e.g., handbook utilization, perceived usefulness of the handbook, active engagement with intervention materials). Intervention condition (Handbook vs Handbook Plus) will be included as a fixed effect and interactions between condition and mediators will be added in a final step. Interactions are included to determine if high responsiveness to the handbook predicts better student outcomes when parents always receive booster text messages.

2.12. Power

Because latent growth curve models use maximum likelihood estimation procedures, they have greater statistical power in testing for group differences in growth trajectories than does a repeated measures ANOVA and thus do not require as large a sample size [53–56]. Muthén and Curran [57] calculate power to detect main effects of 0.20 with five measurement occasions (baseline plus four follow-ups) and a sample size of 900 as $\beta > 0.90(94)$. As clearly illustrated by Zhang and Wang [58], estimates of moderate size ($d = 0.20$) can be detected using latent growth curve models with 5 measurement occasions with power greater than 0.80 with samples as small as 300 cases. The power to detect a modest reduction (0.15) in slope in pairwise comparisons using 5 repeated measures with a sample of 275 in each group and an Type I error rate (alpha) of 0.01 is equal to 0.85. The sample sizes in each condition (control $N = 309$, Handbook $N = 285$, and Handbook Plus $N = 325$) have sufficient power to detect group differences in growth parameters based on these conservative assumptions.

3. Discussion

This study sought to engage parents and incoming college students, via a self-directed handbook, in activities to support communication and conversations about values, attitudes, and family expectations related to the first years away from home. The study provided a practical, self-directed approach for parents and new students to engage with the material, with support from a Transition Support Specialist. The intent of the handbook approach is to reduce barriers such as time and scheduling that might limit a group intervention approach and to provide families opportunities to customize their conversations in ways that are tailored to their family contexts. While we are seeking to achieve this goal, there are some practical limitations to the study. For example, we have limited participation to English-speaking participants only. Another practical consideration is whether there are cohort differences between the two years of recruitment; however, this will be statistically accounted for in our analyses. Finally, implementation challenges can be problematic in self-directed approaches. We will be collecting data to track specific strategies to facilitate high response and retention rates.

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CRedit authorship contribution statement

Brittany Rhoades Cooper: Conceptualization, Funding acquisition, Investigation, Supervision, Writing - original draft, Writing - review & editing. **Laura G. Hill:** Conceptualization, Funding acquisition, Investigation, Supervision, Writing - original draft, Writing - review & editing. **Kevin P. Haggerty:** Conceptualization, Funding acquisition, Investigation, Supervision, Writing - original draft, Writing - review & editing. **Martie Skinner:** Conceptualization, Investigation, Supervision, Methodology, Writing - original draft, Writing - review & editing. **Matthew F. Bumpus:** Conceptualization, Funding acquisition, Investigation, Supervision, Writing - original draft, Writing - review & editing. **Porismita Borah:** Writing - review & editing. **Mary Casey-Goldstein:** Project administration, Supervision. **Richard Catalano:** Conceptualization, Writing - review & editing.

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