

**VillageWhere:**

**Innovative Mobile Technology for Youth with Conduct Disorder and Their Parents**  
**Study Protocol & Statistical Analysis Plan**

**Behavioral Health Research Collective IRB Protocol Number: 030**

**National Clinical Trial (NCT) Identified Number: NCT03065517**

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## Study Process overview

1. [Initial Call/Eligibility Screen/Consent Walkthrough](#)
2. [Action Steps after Consent Call](#)
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4. [Randomize](#)
5. [Orientation Call & Scheduling Assessments](#)
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**Update the Tracking database & Coversheet as needed after each step and point of contact.**

**General Note: Individuals are “Lost to Follow Up” if RAs have attempted to contact them three times, using at least 2 different methods of contact (vm/text/email), over 3 weeks. If the individual contacts after that, proceed with their next steps. Update the recruitment tracking doc accordingly.**

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### **Daily To Do:**

1. Check iKinnect@ebpi.org for new emails (particularly from Calendly) and voice messages (received via email)
2. Check SurveyMonkey for new entries in Referral form and Eligibility screen
  - a. Update the Summative Eligibility Tracking database with new entries in both ‘Referrals Tracking’ and ‘Referrals Received’ tabs
  - b. Skip to step 2 if there is a new eligibility screen entry
3. Check the day of the week folder in Box (i.e., Monday, Tuesday, etc.) for follow ups needed that day
4. Check Eligibility Tracking Database ‘Referrals Received’ tab for any follow up needed
  - a. Note: referrals who have not had initial point of contact don’t have coversheets yet, so RAs need to monitor the tracking database

### **Weekly To Do for Experts:**

1. Send email update to Experts on how many referrals were received from their teams

### **On Fridays:**

- Check all other daily folders for any stragglers (coversheets that were not in the proper folder).
- Do follow ups as needed and place coversheet in appropriate folder for the following week
  - Send reminder emails/texts to participants that have assessments on the following Monday.
- Review the Pending folder and tracking sheet to determine what is needed for the following week and sort into folders accordingly
- Move all coversheets in Friday folder into pending if no follow up is needed the next week, or if completed move it to the ‘Complete’ folder.

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## **Step 1: Initial Call / Eligibility screen / Roll into Consent Walkthrough**

1. Parents interested in participating may schedule an appointment for a phone call via Calendly to learn more about the study via the website: [www.ikinnectapp.com](http://www.ikinnectapp.com)

## iKinnect RCTs Protocol – Parents / Youth

- a. Check the iKinnect@ebpi.org email or the [Calendly scheduler](#) frequently for new appointments and make a calendar event in your own calendar
2. Check SM Eligibility screen for new entries
  - a. Update the Eligibility Tracking sheet with the new entries
    - i. Call to do consent call
3. Check SM Referral form for new referrals
  - a. Update the Eligibility Tracking sheet with the referral
  - b. Call the individual to do the Initial Call
    - i. Leave a vm if no answer and follow up with an email to schedule the initial call using email template (subject line: "<Initial Call>...")
4. Call new referrals to do brief intro to study, eligibility screen, and consent walk through
  - a. If they really don't have time to do it all in one call, make sure to schedule another time to do the call with them
    - i. Follow up every day alternating call/text/email until scheduled
  - b. Send email/text with link to consent form for them to review before call if they'd like
  - c. Send consent form link again during the call to review while talking

### Main points for initial call:

- Identify purpose of call (i.e., learn more about RCTs)
- Provide more information
- If they are interested, provide options for completing eligibility screen:
  - Do it with them on the phone now
  - Send the link via email using the template
- If screen already completed, go into consent

### Voicemail Script

"Hi, this is \_\_\_\_ from the iKinnect Study. We received your <contact information from THERAPIST'S NAME / message expressing interest> and I'm just calling to tell you more about the study. I'd love to tell you more details! Please give me a call or text back at this number xxx-xxx-xxxx to schedule a quick 10 minute call with me. I'll also send you an email after I leave this message in case that is more convenient. Thank you!"

### Initial Call Script <<with parent participant>>

"Hi, this is \_\_\_\_ from the iKinnect study. I'm calling to tell you more about the study, this will take about 10 minutes. Is this still an okay time to talk?

**If no, try to push back a bit to do the call now unless it's clearly not a good time (i.e., at work, meeting). Reschedule if latter, update coversheet, create event in your own calendar, make sure Calendly is up to date If yes, continue...**

Great, thank you!

### Describe app and goal of study

- *We have created an app called iKinnect to help parents set expectations and reward teen's positive behaviors and to help parents monitor their teen's whereabouts.*

## iKinnect RCTs Protocol – Parents / Youth

- Describe study participation briefly
  - *If you were to participate in the study, we would ask you and your teen to use iKinnect or another app called Life360 for 12 weeks. And we would interview you a few times throughout the study to get your feedback.*
- Describe payment
  - *You will be able to earn up to \$240 and your teen will be able to earn up to \$140*
- *Does this still sound like something you'd like to do?*
  - If interested, do screen on the phone and roll into consent if eligible (8 mins)
  - *Do you have a little more time to go through our quick eligibility and consent with me right now? If your teen can be with you that would great, or with your permission we can call them at a different time to go over the same information.*
    - If Yes, go to the eligibility
    - If No, explain RA will send text or email with link to screen and ask to complete as soon as possible

### Eligibility

*Note to RA: make sure to be actively reviewing the answers as you enter them so you can tell parent at the end if they are eligible or not*

- Parent Eligibility questions
- Teen eligibility questions
  - In addition to other eligibility criteria, if Yes to arrested / jail or juvenile detention center / juvenile justice system questions AND/OR scores 6+ on Achenbach, they are eligible
- If eligible, go to Consent
- If ineligible, let them know they are not eligible to participate based on the answers in the survey, thank them for their time and end call
  - If they want to know why, explain reason they were ineligible
- If eligible clarify what kind of services teen is receiving
  - “In our eligibility screen, you said that your teen is currently receiving services for problem behaviors. Could you describe the type of services they are receiving? (i.e., MST/FFT/Strengthening Families/High Fidelity Wraparound services)”
- Make sure we have their full mailing address

### Consent walk through:

*<< send them email or text with link to consent (email template is in ikinnect email)>>*

*I just sent you an email/text with the link to the consent form. If you want to fill it out/review as we talk, I can give you a second to pull that up. Or after we go through all the details during our call today I will send you a text to get your written consent to formally enroll in the study.*

### Describe participation

- *You and your teen will be randomized to use iKinnect or Life360 after the next steps for enrollment are completed, and we will be helping you to get setup with the app when we get to that point.*
- *If you're randomly assigned to use iKinnect, with your permission, we'll reach out to your therapist to get their feedback. If you're okay with this, please sign the release form that I will send to you separately after this call.*

## iKinnect RCTs Protocol – Parents / Youth

- *There are 4 phone calls & surveys, the 1<sup>st</sup> one is right now, then we'll do one once a month during your 12-week participation*

### Describe payment

- You'll be paid up to \$240, and your teen will be paid up to \$140; we'll send you a check after each survey is completed and the consent form lists the amount for each of these.
- *Because it is very important for the research to get the surveys completed on time, we will be able to provide 2 bonuses. For you, each bonus will be \$30 and for TEEN each bonus will be \$20*
  - *You will get the 1<sup>st</sup> bonus when you complete 3 out of the 4 surveys*
  - *And the 2<sup>nd</sup> bonus when all 4 surveys are completed*
- *The checks will be made out to you, PARENT, and will be mailed from Chase Bank, so please keep eye out for Chase envelopes.*

### Risks

- *The consent form also includes minor potential risks involved with participation, but I will verbally go through them here and explain what we will be doing to minimize these risks*
  - *The minor potential risks include the following: you and/or your teen may feel uncomfortable sharing your opinions during our phone calls, you may disagree about how to use the app, you may feel uncomfortable about using the app in a public space, and the others have to do with confidentiality, privacy, and feeling pressured to participate.*
    - *Right away, I want to let you both know that both of your participation in the study, at all times, are completely voluntary. You should never feel pressured to do anything in the study that you do not want to do.*
    - *Regarding the phone calls we do, as I mentioned before, we will only be asking for your feedback about your experience with the app. We will not ask for personal stories. We will however encourage you to tell us everything that is on your mind –positive and negative feedback- because that will be extremely helpful for us as we try to make improvements to iKinnect.*
    - *In terms of your use of the app – whether that is iKinnect or Life360 – we will ask you both to use the app on a regular basis, whatever that means to you. After your next steps are done, we will schedule another call to orient you to the various feature in the app that you'll be using, but from there you will be able to decide how/when/where you want to use the app.*
    - *To safeguard confidentiality and privacy, we will be assigning both you and your teen with unique study identification numbers. These study ID numbers will be associated to the feedback you provide – whether that is verbal over the phone or the answers you select in the survey questions – in this way we are de-identifying your information so it is basically not traceable back to you. The surveys will also ask for the last four digits of your cell phone number just to make sure we know who filled out the survey and make sure to send you the payment.*
- *Your participation will not affect your legal status or any services you may be receiving*
- *<say this if didn't say it while explaining minor potential risks> Both you and TEEN's participation are completely voluntary at all times, and you can choose to decline/stop at any time.*
- *Finally, We will also ask for your agreement on something call the HIPAA Authorization, which is something we're required to get because this is a research study involving people and we collect information that is considered "protected health information". For us we would only have your*

## iKinnect RCTs Protocol – Parents / Youth

*name/address/phone number, demographics, and that your youth is receiving services. The authorization just gives us permission to disclose PHI if we are required to do so for auditing purposes. This information is federally protected from being used in any kind of legal proceeding and it is essentially only accessible by the research staff.”*

- *Now that you know more about the study, are you still interested?*
  - If Yes, Get parent's consent for teen: *PARENT, do you give permission for your teen to participate in our study?*
    - *Would it be okay for us to contact your teen separately? Or would you prefer it to be at a time when you will also be there?*
      - If yes to contacting teen separately,
        - *What is the best way to reach the teen?*
        - *We'll give them a call later today, if you see them before that time, please let them know I'll be calling*

Let them know Next Steps:

- *As I mentioned earlier, I will send you*
  - *A text with a consent statement, if you don't have any questions and understand everything we talked about today, would you be able to take a look at that and send a text response back while I'm on the phone with you? Please let me know right away if you have any questions or concerns.*
  - *<<if they want to review consent>> an email with the link to the consent form, which has everything we just talked about here. Please take a look at that with TEEN and provide your electronic signatures together.*
- *In the email, there is a link that will take you to the first set of study surveys I mentioned earlier. You will need your Study ID number for this. If you have something to write on, I can tell it to you now.*
  - *If driving or otherwise can't take down the ID number, let them know you will text it to them*
  - *To get you and your teen speedily through the enrollment process and ready to go for the 12 weeks, can we plan to do our next call later this week/early next week? This just means that your baseline survey and your teen's baseline survey will need to be completed before we do that call.*
  - *This next call will be so that we can walk you through setup of the app that you will be asked to use in the study and will take about 15-20 minute long*

## Go to Step 2 for Action Steps

### Assent Call with Youth / consent with 18 youth adult

- Go through the Youth Assent Form with them (don't need to say it word for word or in that order)
  - Main points:
    - Participation is completely voluntary
    - Payment information
    - App randomization
    - Baseline, week 4, week 8, week 12 + brief phone call interviews
    - Potential minor risks and how we minimize them

## iKinnect RCTs Protocol – Parents / Youth

- Answer questions
- RA fill out the form on SurveyMonkey
  - **Ask and get Verbal answers:**
    - ***Do you understand that your participation is completely voluntary?***
    - ***If you are willing and interested, do you want to participate in our study?***
  - **If parent sent text consent, also send Text Consent language to teen and get their written consent**
- *I will send you an email/text right after this with the link to your first survey, which will take about 15-20 minutes. Do you think you'll have time to do that tonight?*
  - <if orientation call was scheduled with parent already> *Our next call with you, me, and your parent is scheduled for xx/xx at TIME. You will need to complete these surveys before then, do you think that's doable?*
  - Provide study ID

Go to Step 2

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## Step 2: Action Steps after Consent Call

1. Send appropriate links and materials to parent (use template email or text)
  - a. Text Consent language:
    - i. **For Parents:** "By texting back Yes, you confirm that you have verbally received study details and provide your consent for yourself and your teen to participate in the study. This includes consent for iKinnect data collection and limited sharing of personal health information as described in the HIPAA authorization."
    - ii. **For Assent Teens under 18 years old:** "By texting back Yes, you confirm that you have verbally received study details and provide your assent for yourself to participate in the study. This includes assent for iKinnect data collection and limited sharing of personal health information as described in the HIPAA Authorization."
    - iii. **For 18-year-old Teens:** "By texting back Yes, you confirm that you have verbally received study details and provide your consent for yourself to participate in the study. This includes consent for iKinnect data collection and limited sharing of personal health information as described in the HIPAA authorization."
  - b. For Emails:
    - i. Attachment of Teen Involvement PDF
    - ii. Consent form link
    - iii. Correct baseline survey link
      1. Go to the correct SurveyMonkey form (note: all new assessments have "Rev2" in the title except parent baseline which is "Rev4")
      2. Click Collect Responses
      3. Scroll down and click Web Link under Add a new collector
      4. Do not make any customizations to the weblink number or link
      5. Edit the setting: Anonymous Responses to "On" and make sure the "your changes have been saved" message comes up at the top right of the screen

## iKinnect RCTs Protocol – Parents / Youth

- a. If this changes saved confirmation message doesn't pop up, click anywhere outside of that settings box – it should then pop up
6. Copy the link and send to yourself (via slack or email) and copy/paste into text to send to participant
7. Open Participant tracking database and record the weblink number in the appropriate column
  - a. Do not track weblink number in coversheets
- c. Release Form via SignNow --- okay to do this after enrollment is complete
  1. Login to SignNow using iKinnect credentials
  2. Go to Templates
  3. Click More > Create a Copy
  4. Go to Documents
  5. Click on the newly created copy and enter in known information
    - a. Click "Text" under "Edit & Sign" in the menu bar > add text boxes to enter parent's name, teen's name, and therapist's name in appropriate places
    - b. At bottom of form where it says: "This release of information will expire 1 year from today's date, on:", add the expiration date
    - c. Add signature boxes for parent and teen signatures
    - d. Add date boxes
  6. Click Done
  7. Click Invite to Sign
  8. Paste Parent's email into Signer 1 and click Send Invite
- d. Text SSID number if this was preferred

2. Text/email (preferred method) Youth baseline survey link to the teen after assent
  - a. If Youth is 18, send them separate email (subject line: "<Elig/AdultYouthConsent>") with Adult Youth consent form:
  - b. Text link to SSID if not given verbally
3. Update the Names-SSID link in dropbox
  - a. Parents and their teens will have the same last two digits. For Example: If Parent is 1001, then teen would be 2001, and therapist would be 3001
4. Create a Coversheet for the eligible dyad and keep notes of all interactions in the log
5. Update Summative Participant Tracking Database
6. Review eligibility screen again and Export data (export data even if they are not eligible)
7. Follow up with Parent / Teen every other day alternating call/text/email until consent form and baseline surveys are complete

### If Eligibility Screen was completed without RA:

1. Review eligibility questions and determine if eligible or not
  - a. Follow above steps to export the data into the eligibility tracking database
2. If adult wanting to participate is not the legal guardian but they are the primary caregiver, bring to LAD/CS for case-by-case determination.
  - a. Must do consent call with the legal parent/guardian and have them sign the consent & HIPAA for the youth – make sure to specify this during consent call if LAD/CS approve participation.
3. If they said Yes to the questions about teen arrest / jail or juvenile detention center / juvenile justice system involvement AND/OR have a score of 6 or greater on the Achenbach, they are eligible

## iKinnect RCTs Protocol – Parents / Youth

- a. In the Achenbach Total column of eligibility tracking database - Click and drag down the bottom right corner of the cell in the row above to copy the formula
- b. DO NOT COPY/PASTE the cell in the row above – this will give you the total of the row above
4. Review screen for any skipped questions that need follow up; note these as follow-up items during phone call

If individual is ineligible on core criteria (i.e., age, English, smartphone), they will have received the ineligible screen automatically in the survey; however, if deemed ineligible based on the questions that need more review (i.e., life360 use, arrest/jail/JJ/Achenbach), RA needs to send the ineligible email (subject line: <Ineligible>...").

### If UNSURE about eligibility:

1. Flag any questions and consult with Cindy & Linda
  - a. Call/email individual for clarification of eligibility and/or Informed Consent

### Voicemail Script if FOLLOW-UP Needed to Determine Eligibility:

Hi, this is \_\_\_\_\_ from the iKinnect Study. I'm calling to talk with you about your participation. We just have a couple of questions to clarify a couple answers you provided in the online questionnaire. I will send you an email after leaving this voicemail message in case that's more convenient for you. Please reply to that email or call me back at (phone #) at your earliest convenience. Thank you!

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## Step 3: Action Steps after Consent Form & BL are Complete

1. Consent form
  - a. When consent form is completed, check to make sure all questions are completed and that they agree to participate in the study. Make note if they answer 'No' to any of the authorization questions – RA needs to follow up with parent to see if they meant to say No and elaborate to help them understand that section.
    - i. **If adult participating is not legal guardian make sure the teen's legal parent/guardian signatures have the name of actual legal guardian (there are a few places on the consent/hipaa)**
    - ii. **Make sure e-signature for Youth is actually Youth and not the parent's name**
2. Log the consent completion into the database and cover sheet
3. **Send Parent a copy of their consent form and HIPAA authorization and remind them to complete baseline if they haven't already done so.**
4. Monitor SM for completed baseline assessments for both parent and youth
  - a. Call or mail or text every other day until completed;
  - b. log in 'PaymentRequests' tab in tracking database when completed
5. Paste demographics portion from Eligibility screen into 'Demographics' tab of tracking database.
6. Monitor SignNow/ ikinnect inbox for completion of release form
  - a. **After release form is signed** email a PDF of the form to the therapist using email template
7. See Step 4 to Record randomization categories for participant taken from the demographics portion into the 'Randomization' tab in the tracking database

## Step 4: Randomize

1. Open the participant tracking database, go to ‘Randomization’ tab
2. Enter SSID of youth; parents are yoked to youth so no need to enter their ssid
3. Complete all other yellow highlighted columns (using the information gathered in the screen)
4. Let Julie know to do randomization
  - a. For Randomizer:
    - i. Open Minim Py
    - ii. Enter the randomization categories
    - iii. Record Date Randomized, UI number, and Condition in the ‘Randomization’ tab in the tracking database
    - iv. Let RA know once participant is randomized

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## Step 5: Orientation Call – download the app & schedule assessments

1. If not already scheduled, call/email to schedule the Orientation call (~15-20 mins)
  - a. **ideal to have Parent and Teen together, but if you get ahold of parent first, do call with them and schedule another time to orient teen**

### **Voicemail Script:**

Hi \_\_\_\_, this is \_\_\_\_ from the iKinnect study. I’m reaching out to schedule a quick call, so I can orient you to the app you and your teen will be using for the study and a few final details about your participation. At your earliest convenience, please give us a call back at xxx-xxx-xxxx. Thanks!

2. If they call you back
  - a. And it is a good time for you to talk: Go through the script below
  - b. And it is not a good time for you to talk: Schedule a time you can call them back.
  - c. Update Coversheet / tracking database/ your calendar/ Calendly once scheduled
3. Try to schedule assessments at the end of this call with both parent and teen
4. **Send the Tamper Proof doc (there’s an iKinnect version and Life360 version) to parent if their teen has an iphone**

### **Call Script:**

Hi \_\_\_\_, this is \_\_\_\_ from the iKinnect study. Thank you again for your participation! I’m calling today to help get you set up with the app you’ll be using for the research. We have done the random assignment for you and your teen, you will both be using <<iKinnect/Life360>> during your participation.

**If randomly assigned to iKinnect and has a service provider (case manager, therapist, etc), make sure we have the service provider’s contact information – get from parent and record in eligibility tracking database**

### **Steps to Downloading iKinnect and getting set up:**

1. Go to app store / play store

## iKinnect RCTs Protocol – Parents / Youth

2. Search iKinnect (spell it for them)
3. Install the app
  - a. Make sure they say yes if message pops up asking to use location services (must say yes to it pulling location even when app is not in use, i.e., Always) – this is more for iPhones (I think)
  - b. And yes to notifications question if it pops up
4. Open app
5. Parent Create new account by clicking Sign Up
6. Complete all profile/account set up pages
  - a. After parent completes their profile setup, iKinnect will ask for Youth's phone number
7. Teen will receive a text message prompting them to download iKinnect
  - a. Go through same process as parent – install app and create new account
8. Stay on the phone with them and help them set up a challenge card – do not rush because they will need to be using these settings for the 12 weeks
  - a. Make sure teen accepts the challenges when created
  - b. Make sure they both know where everything is

### Steps to Downloading Life360 and getting set up:

1. Send parent the guide
2. Go through each step of setup with them
3. Go through steps with youth user and make sure they are connected with parent in the app
4. Make sure they each know that free version is the one they can use and what to look out for when the app asks them to upgrade to premium

### For All:

Great, so we are all set up now. We will consider this week to be Week #1 for the study. Before we get off the phone, I would love to schedule the three study calls with you and YOUTH. Each call would take about 10-15 minutes and would be done individually, so I would talk with you PARENT and then with TEEN, or vice versa.

### Scheduling

1. The week the app is downloaded is considered "Week 1"
  - a. If it's a Friday, consider making the next week "Week 1", especially if iKinnect, to allow dyad to have the full 4 weeks of experience with the app before first interview
2. Schedule a call for Week 4, Week 8, and Week 12 assessments in the respective weeks for Parent and Teen separately
3. Send the confirmed dates and times to the participant for future reference using the template email (this also has the tamper proof attachments if applicable)
4. After scheduling, log all the dates and times into the Coversheet / tracking database/ your calendar and update Calendly to block out those times.

Thank you both very much! I will send reminders when it gets closer to our appointments. But feel free to call or text me if you run into any technical difficulties before then.

Thank you, have a great day!

## Step 6: Assessment Calls

1. Open the Semi-Structured Interview Template
2. Save as 'SSID.iKinnectRCTInterview.WeekX' in the Interview Notes folder on Box
3. Call participant at scheduled time, script below
4. If participant doesn't answer, leave voicemail below and email or text follow up.
  - a. Alternate call/email every day until you reach them to reschedule
5. If they call you back
  - a. And it is a good time for you to talk: Go through the script below
  - b. And it is not a good time for you to talk: reach out to other RA or schedule a time you can call them back.
  - c. Log the call in the cover sheet and tracking database

### **Voicemail Script:**

Hi \_\_\_\_, this is \_\_\_\_ from the iKinnect study. I'm calling for our study call scheduled at X:XX today. Please give me a call back here at xxx-xxx-xxxx if this time still works for you. If not, let me know another time that will work for you this week. I'll also send you a quick email/text in case that is easier for you. Thanks!

### **Call Script:**

Hi \_\_\_\_, this is \_\_\_\_ from the iKinnect study. Thanks again for your participation! I'm calling today for your <>Week 4, 8, 12>> study appointment. Is it still a good time for you?

Great! Today I will be going over a list of questions about your experience using <>iKinnect/Life360>> over the phone and then I will send you the link to your study surveys afterwards.

<>Administer the Semi-Structured Interview, taking detailed notes during conversation; exclude any personal identifying information such as names/locations>>

Thank you for answering those questions! I'll go ahead and send you an email/text <>their preference>> with the link to your surveys for today. We expect these surveys will take 15-20 minutes to complete. You'll also need your Study ID for these surveys. If you have something to write on, I can tell it to you now to make sure you have the right number. <>we want to be able to tell them verbally, but if they don't have anything to write on/with: I can text it to you>>.

If you run into any technical difficulties or have any questions as you go through the survey, please don't hesitate to call or text me back here.

You can expect to receive a <>Parents: \$40 for week 4; \$50 for week 8; \$60 for week 12 parents | Youth: \$25>> check in the mail within the next 30 days. It will be coming from Chase Bank so please make sure to keep an eye out for that.

I just want to double check that we have the correct mailing address for you. We have <>get address from eligibility tracking database>>.

**For Week 4 & 8:**

Our next appointment will be on Month Day @ Time Time Zone. I will remind you when it gets closer to that time, but if you need to reschedule, please let me know at any time. Thank you!

**If Week 12 interview, check how many surveys they completed on time and remind them about bonuses:**

Today was the last study call, your participation will end after you complete the final set of surveys. Thank you very much for all your time in participating and completing these survey, we know it does take a lot of time and we really appreciate your help! Your free access to iKinnect will start after you and TEEN complete the week 12 survey, we will send you an email to let you know when it starts. Thank you!

6. Text or email link to Week 4, 8, 12 surveys
7. Monitor SM for completed survey
8. Follow up via text/email (participant's preferred method) every day that week until complete
9. Update Coversheet/tracking database when complete and fill out 'PaymentRequests' tab of tracking database

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**Step 7: Closing Steps**

1. Make sure all bonus payments are requested
2. Make sure to get all parent/youth participants 3 months access to iKinnect

## STATISTICAL ANALYSIS PLAN

**Data Analysis:** Regarding the **handling of data**, procedures will be similar to those in previous studies conducted by the PI (Dimeff) for the managing, entering, filing, and analysis of data. Data are monitored through a data tracking system from the beginning of a given assessment through completion. Data will be entered online using an encrypted, secure online assessment tool such as RedCap. Missing values are coded as to reason missing (e.g., 'subject unable to be located,' 'subject refuses to answer,' etc.). All data are cleaned for logic and other types of errors using SPSS. With regards to **dropouts and missing data**, we plan to gather data for all participants at all time points (including from those who stop using VW). This will allow us to conduct primary analyses on the intent-to-treat sample. To minimize missing data, we have included built in incentives (i.e., bonus payments for completing three and again for completing all four time points). To the extent there is question skipping or missed assessments, the software and analysis method we have chosen provides several options for the handling of incomplete data. Preference will be given to those methods for which the assumptions (e.g., Missing at Random) are plausibly met and that have the least biased parameters.

**Analysis Strategy.** We will use the Generalized Linear Model (GLM), a regression-based approach designed to overcome the limitations and criticisms of ANOVA. It provides greater flexibility in that it can analyze a variety of commonly encountered outcome distributions (e.g., continuous, count) and can calculate robust standard errors which are less sensitive to skewness. Specifically, we will conduct our repeated-measures analyses using a version of GLM called Generalized Estimating Equations (GEE), which do not rely on the overly restrictive (and often incorrect) assumptions made by Repeated Measures ANOVA about the covariance matrix that can lead to misspecification. Like Hierarchical Linear Modeling (HLM), GEE has an advantage over ANOVA in that can test the use of different assumptions of the covariance matrix to determine the one best fitting the data; it can also include participants who are missing data at some time points. We will use the SPSS statistical package version 23 and GEE for all hypotheses concerning outcomes for parents and youth. For each outcome, we will specify the correct distribution and compare fit indices to identify the covariance matrix best fitting the data. All hypotheses relate to change over time, and so the multiple time-points will be treated in the GEE analyses as nested within the individual. Also, we will treat intervention condition and time as categorical, dummy-coded predictors; the control condition and baseline scores will serve as the reference points. The parameter of interest will be the Time X Condition interaction, and the Type III statistic will serve as an omnibus test of whether the two conditions differed in change over time. Regression coefficients will indicate at which follow up time points the conditions showed differential change from baseline.

**Statistical Power Considerations.** We conducted power analyses focused on the ability to detect statistical significance on the key parameter of interest, the Time X Condition interaction. Power analyses assumed equal size groups,  $p \leq .05$ , power of .80, and two-tailed tests. Otherwise, findings from our pilot study guided assumptions. In that study, we found an average effect size of Cohen's  $d = .42$  (a magnitude between low medium and low), and between-time point correlations ranging from .36 - .81 (average  $r = .57$ ). To ensure that we enroll a sufficiently large sample, we computed our power calculations using the pilot study numbers that would require the largest enrollment. Specifically, we assumed correlations of .36 and a desire to detect a smaller effect size of  $f = .15$  (similar to  $d = .30$ ). Using GPower's utility for the GLM, we found that we would need a total sample size of 80. To account for the possibility of attrition (20%), we increased to a target enrollment of 100.