Cell Phone Support to Promote Medication Adherence Among Adolescents and Young Adults With Chronic Illness

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Protocol

Abstract

Objective: Adolescents and young adults (AYA) living with chronic illnesses often struggle to adhere to daily oral medication regimens. Mobile health (mHealth) interventions are a promising avenue to support AYA in improving adherence, such as through delivering human coaching following the Supportive Accountability Model via mobile devices. AYA have reported increased use of and preference for text message communication over phone calls, so more investigation is needed to understand how cell phone support could be efficaciously delivered.

Methods: A randomized, controlled, 3-arm pilot trial will evaluate the impact of Cell Phone Support (CPS) on medication adherence. Conditions will be CPS delivered by phone calls (CPS-C), CPS delivered by text messages (CPS-T), or automated text message reminders (ATR). Participants will include AYA with various chronic illnesses (i.e., solid organ transplant, epilepsy, type 2 diabetes, sickle cell disease), aged 15-20 years ($N = 60$). Randomization will be done via stratified blocks based on sex assigned at birth and focal diagnosis. Outcomes will include intervention engagement, participant satisfaction, and medication adherence, assessed using multi-method measurement. Additionally, focus groups will be used to assess the impact of CPS and understand how patients and healthcare providers experience the intervention.

Research Background:

In the US, there are 2 million AYA living with chronic illness, many of whom struggle to develop vital illness self-management skills. Over half of AYA are nonadherent to their medication, resulting in detrimental health outcomes, increased healthcare expenditures, and poorer quality of life (Rapoff, 2010). Since over 95% of AYA use cell phones (Lenhart, 2015),

mobile health (mHealth) technology is a promising method for delivering self-management interventions. To date, several mHealth interventions have demonstrated efficacy for improving medication adherence in a cost-effective manner. Unfortunately, of the existing adherence-promoting mHealth interventions, nearly all suffer from the same significant limitation: they are disease-specific, which significantly limits the pace of implementation. A general, flexible mHealth intervention for AYA living with diverse chronic illnesses could meaningfully accelerate the timeline for implementation of adherence-promoting interventions in widespread practice.

CPS is an adherence-promoting mHealth intervention that has been piloted separately with AYA with HIV (Belzer et al., 2014) and solid organ transplants (Sayegh et al., 2018), showing evidence of efficacy for increasing medication adherence. The current version of CPS includes short phone calls (<5 minutes) made each weekday by a human coach to provide social support, medication reminders, problem-solving coaching, incentives for answering calls, and referrals to other services. CPS calls focus on assisting AYA in identifying and accessing resources and support from their natural environments, such as finding ways they can receive needed help from their families, peers, medical teams, and communities. Pilot results indicate that CPS may promote medication adherence in two very different medical conditions; however, participant feedback and study enrollment rates suggest adaptations are needed to improve the acceptability of CPS. Many pilot participants indicated they would prefer to receive CPS through text message conversations with the AF, instead of traditional phone calls. This finding is consistent with national trends in technology use and preference; in the past decade, AYA have reported believing text messaging is easier, faster, less socially awkward, and more confidential than talking on the phone (e.g., Evans, Davidson, & Sicafuse, 2013). Although some promising

two-way, interactive text message adherence interventions exist (e.g., Dowshen et al., 2012), all have been automated interventions, not live, real-time conversations between human Coaches and AYA patients.

Although AYA prefer texting, it is unknown how delivering CPS through this communication mode could impact its effect on adherence. What most distinguishes CPS from other mHealth interventions is that human Coaches deliver the intervention in real-time, live phone calls, in contrast to the automated reminders which have proliferated in the adherence literature. The Supportive Accountability Model provides a framework for understanding how technological aspects of mHealth could impact the provision of adherence-focused support [7]. This model describes how a positive bond with a credible, caring person creates a sense of accountability, which in turn increases engagement in health behaviors. Counterintuitively, text message interaction could enhance, rather than dilute, supportive accountability because individuals tend to make more positive attributions of their communication partners and engage in more self-disclosure when using "lean media" that does not include the voice of the communication partner (Mohr, Cuijpers, & Lehman, 2011). These findings, along with current AYA technology preferences and practices, suggest CPS may be more acceptable, feasible, and effective if delivered by live, real-time, interactive text messaging with human Coaches instead of traditional phone calls.

Research Aims:

The aim of this randomized pilot trial is to evaluate the acceptability, feasibility, and efficacy of CPS delivered by phone calls or text messages to AYAs with several distinct chronic illnesses, in preparation for a fully-powered multisite, effectiveness-implementation hybrid trial. We propose 1) assessing the feasibility, acceptability, and efficacy of CPS for improving

medication adherence, 2) investigating the impact of delivering CPS through live text messages versus phone calls using quantitative and qualitative methods, and 3) evaluating patient and provider views of CPS to guide future implementation work. The proposed research follows the conceptual model (Figure 1), positing that CPS will promote adherence through engaging AYAs in calls or texts with a human coach providing social support. We predict that delivering CPS by text message will increase feasibility and acceptability, perceived social support, and medication compared to voice delivery. This study extends the literature on mHealth to promote AYA adherence in several ways. First, although increasingly interactive and personalized *automated* text message interventions are proliferating in the adherence literature, there have been no randomized trials published evaluating the impact of *live* text message conversations on medication adherence among AYA. Second, rather than focusing on a single focal diagnoses, this study will enroll AYA with *diverse* chronic illnesses. This approach could greatly increase the number of patients having access to self-management support, therefore leading to a greater reduction in negative healthcare outcomes, costs, and burden. Third, despite comprising over 20% of the US AYA population, Latinx patients make up only 5% of mHealth study samples (e.g., DeKoekkoek et al., 2015). The proposed study will enroll >50% Latinx participants, based on pilot data, increasing national representativeness of the mHealth literation [4].

Methods:

Setting and Sample

This study took place at Children's Hospital Los Angeles (CHLA), a large, urban, quaternary care, free-standing children's hospital that services approximately 36,000 unique AYA patients and cares for nearly one-third of LA County's Title V beneficiaries. As a safety net hospital, CHLA serves the most vulnerable children in the community, many of whom are at

high risk for gaps in care and adverse outcomes as they transition to adulthood. Participants in this study including patients who met the following inclusion criteria: 1) 15-20 years old at enrollment, 2) a patient at CHLA, 3) taking at least one oral medication per day, 4) provider and patient agreement that medication adherence is currently <80%, 5) Access to a cell phone, and 6) ability to speak and understand English. Participants were excluded if they had a cognitive impairment that precluded them from engaging in the consent/assent process or study protocol. Participants with diagnoses of autism spectrum disorder or intellectual disability were eligible as long as they were able to describe the purpose of the study, risks and benefits of enrolling, and summarize the research procedures in their own words. Non-English speaking patients were excluded because interventions were only developed in English at this stage. In addition, health care providers were enrolled to participate in focus groups and interviews. For healthcare providers, inclusion criteria was: 1) Status as a healthcare provider at CHLA providing care to adolescent and young adult patients taking daily oral medication, and 2) working in a CHLA subspecialty clinics which had agreed to refer patients to this study.

Design

After passing eligibility screening and completing pre-treatment questionnaires, participants will be randomly assigned (1:1:1) to one of three 12-week groups: CPS delivered through voice-based phone calls (CPS-C), CPS delivered through text messaging (CPS-T), or automated text message reminders (Automated Reminders). A research colleague outside of the team used rand( ) function in Excel to create randomization blocks of 6 by sex assigned at birth and focal diagnosis. I hope to prevent substantial confounding by using stratified block randomization. For example, among the first 6 female participants with organ transplants, 2 would be assigned to CPS-C, 2 would be assigned to CPS-T, and 2 would be assigned to ATR.

The research colleague placed cards in sealed envelopes indicating the group assignment, and after the participant signed the consent form, the PI opened the envelope and informed the participant of the group they had been assigned to.

Procedures

This study was approved by the Children's Hospital Los Angeles Institutional Review Board. Adult patients provided informed consent, and parents provided permission and minor participants providing assent. Adult participants or parents of minor participants signed a waiver of HIPAA to participate in the study since text-messaging is not a HIPAA compliant form of communication. Surveys were administered via REDCap, with up to 3 invitations sent by text message over the course of one week, at pre-treatment (0 weeks), mid-treatment (6 weeks), post-treatment (12 weeks), and follow-up (18 weeks). Participants were compensated with a $50 gift card for the pre-treatment surveys, and $25 gift cards at each of the three followed assessment periods. Focus groups with participants were held in same-study-condition cohorts via WebEX after at least 2 parcipants had completed the 12-week intervention. Participants were compensated with a $20 gift card for joining the focus group. Participants received a $15 gift card for mailing back their MEMS Cap at 18 weeks. A community advisory board (CAB) consisted of $N = 8$ 18-24 year old current and former patients was recruited in June 2020. The CAB meetings bimonthly via WebEx to provide guidance and feedback on each stage of the research.

Interventions

Cell Phone Support. A human coach delivered CPS either by phone calls (CPS-C) or live, real-time, two-way text messaging (CPS-T), between 3-5 days per week for 12 weeks. Participants

were given the choice of the frequency of their calls/texts based on CAB guidance. Coaches were undergraduate research assistants earning course credit at the University of Southern California. They will participate in a single, 2-hour training on the promotion of medication adherence, with 1 hour of phone-based group supervision every 2 weeks throughout the trial, similar to the prior pilot studies of CPS [3,4]. Coaches were trained in delivering CPS through phone calls (CPS-C) and text messages (CPS-T), and delivered both CPS conditions. Each CPS interaction will last no more than 5 minutes, following the outline below. Participants received monthly incentives worth $40 contingent upon answering over 75% of the Coaches calls or text messages. Examples of CPS call content from the organ transplant pilot study [4] include: 1) coaching patients to reach out to their social worker for assistance navigating insurance changes, 2) teaching patients how to use cell phone alarms to remind them to take medications, 3) supporting patients to identify ways a parent could help them wake up on time to take scheduled doses on weekend mornings, 4) assisting patients to devise strategies to link medication-taking with daily routines, e.g., brushing teeth, and 5) making referrals to family therapy when family conflict interferes with medication-taking. CPS is based on theories of social support, in that the COACHprovides support for adherence directly to the AYA patient while optimizing the support available from their natural networks, such as parents, peers, romantic partners, healthcare providers, or others.

Coaches were trained to refer patients to their providers during daytime hours or the physician-on-call during night hours if they make medical complaints, ask about their health status, or express confusion about their prescribed medications. Healthcare provider and CAB feedback indicated that it is important for physicians to have accurate knowledge of patients' medication adherence in order to monitor health and safety, and adjust medication dosages effectively. To ensure that health care providers can monitor and follow-up on adherence issues

impacting health, we will alert them to patients' nonadherence, whether disclosed in a CPS contact or in response to the automated text reminder, after fully explaining this in the informed consent process. Despite the challenge to internal validity, providers will be informed as to which condition their patients are assigned, to allow them to integrate the mHealth intervention into their treatment plan. The PI informed healthcare teams of participants' engagement in the CPS interventions, barriers to adherence, and progress on improving adherence in a summary email at least every two weeks.

Automated Text Reminders (ATR). The comparison condition will include automated text message reminders (ATR) modeled after an intervention used with a sample of AYA liver transplant patients, which was associated with increased adherence based on medication blood levels [14]. Specifically, text messages stated: "It's time to take your medicine! Please reply with any text." Texts were sent through automated survey invitations feature in REDCap, using Twilio. When participants enrolled, they selected the time(s) of day they preferred to receive their text reminders, and the PI checked their expressed preference against the electronic health record to confirm the frequency (i.e., once daily, twice daily) was consistent with their medication list. If participants confirmed receipt of at least 75% of their automated text reminders each month during the 12-week intervention, they received a $40 gift card as an incentive. The PI informed healthcare teams of the frequency with which participants were confirming their automated texts in a summary email at least every two weeks.

Intervention Training and Fidelity

CPS interventions were delivered by 6 "adherence facilitators" or "coaches" who were undergraduate research students enrolled in experiential research course at University of

Southern California (either in Department of Psychology or Department of Preventive Medicine). Coaches underwent a background check and completed the CITI Human Subjects Protection course, TrojanLearn Mandated Reporter course, and Praesidium Social Media Safety course, as recommended by the USC Department of Risk Management and Insurance. Coaches participated in 2 4-hour training sessions to learn the intervention, involving a combination of lecture and role-plays with feedback. Coaches participated in weekly group supervision with the PI, and all calls and texts were recorded, uploaded via HIPAA-compliant REDCap file upload link, and reviewed by PI using a fidelity checklist. Coaches completed a short survey after each contact to record whether the participant answered their call or text, whether they reported taking their medication since the last call, topics covered in the call, and any referrals given. Additional details about the CPS intervention can be found in prior publications [3,4].

Measures

Demographic Variables and Covariates. At pre-treatment, participants reported their age, sex assigned at birth, gender identity, racial identity, and ethnicity. They also reported their highest level of education, whether they had a job, and with whom they resided. In addition, they described their parents' highest level of education and completed the Family Affluence Scale II (FAS II; Boyce, Torsheim, Currie, and Zambon, 2006). The FAS II is a 4-item scale that can be summed, and used to categorize participants as low socioeconomic status (0-2), medium socioeconomic status (3-5), or high socioeconomic status (6-9). Previous studies have concluded that the FAS II is a valid and reliable measured of socioeconomic status (Liu et al., 2012). At follow-up, participants were asked to report on how COVID-19 had impacted their lives, using the COVID-19 Exposure and Family Impact Scales (Kazak et al., 2021). Finally, medication complexity will be calculated based on data in the electronic health record. We will follow the

procedures described by Lilly et al. (2013) in calculate a Medication Regimen Complexity Index (MRCI) calculated a score for the focal diagnosis and the non-focal diagnosis.

Primary Outcomes: Adherence Dependent Variables

Self-Reported Adherence. In this study, medication adherence over the past 3 months was measured by a 3-item visual analogue scale (VAS) developed by Walsh, Dalton, and Gazzard (1998). The VAS uses percentage scales that contains the percent (%) value from 0 to 100 in which each point on the scale suggests the percent of time of medication adherence within a specified duration of time: 0% would mean "none of the time" or "never"; 50% would mean half of the time; 100% would mean "all of the time" or "always", and numbers in between would mean amounts between "never" and "always" (Walsh, Dalton, & Gazzard, 1998). For each time frame, three visual analogue scales are provided, assessing 1) the percentage of the time patients took their medicine, 2) the percentage of the time patients took all the doses for the day, and 3) the percentage of the time patients took their medicine according to the directions (Walsh, Dalton, & Gazzard, 1998). Administering self-report adherence surveys by computer may decrease social desirability bias (Stirratt et al., 2015).

MEMS Caps Adherence. Participants (and caregivers, in the case of minor participants) will be oriented to using MEMS caps for one of the medications they take daily of their focal diagnosis (i.e., immunosuppressant for transplant, antiepileptic drug for epilepsy, hydroxyurea for sickle cell disease, metformin for type 2 diabetes). Microelectronic circuitry records the dates and times the caps are opened. We will calculate the percentage of prescribed doses that appear to have been taken through week 6, 12 and 18. MEMS caps are considered the "gold standard" in

adherence research and show moderate validity with both patient populations (Gerson et al., 2004; Cramer et al., 1995).

Electronic Health Record Adherence Indicators. Many of the focal diagnoses have regular labs collected as part of usual clinical care. For example, medication trough levels are usually collected periodically for the purpose of therapeutic drug monitoring for AYA living with solid organ transplants (i.e., immunosuppressant medications) and epilepsy (i.e., anti-epileptic drugs.). For other diagnoses, regularly collected labs are considered partially indicative of adherence, such as the hemoglobic A1C test for type 2 diabetes and mean corpuscular volume/fetal hemoglobin for sickle cell disease.

Secondary Outcomes: Psychosocial Dependent Variables

Participants were invited via text message to complete the following surveys at all four assessment periods., via RED Cap.

Social Support. Participants responded to the MOS Social Support survey to report on their perceived social support (Sherbourne & Stewart, 1991). There are three subscales that comprise the MOS: emotional/informational support, tangible support, and affectionate support.

Self-Efficacy. Three items assessed self-efficacy for taking medications as prescribed. The items included the following: “How sure are you that you can take the right amounts of your medicine at the right times?”; “How sure are you that you can do better with taking the right amounts of your medicine at the right times?”; and “How sure are you that you can take the right amounts of your medicine at the right times even if you were very tempted not to?” These items were scored using a 5-point Likert scale ranging from 1 (very sure I can) to 5 (very sure I cannot). For the current study, responses were reverse-coded and items summed to form a

composite self-efficacy score (max possible score = 15.0) as in (Kolmodin MacDonell et al., 2016).

Depression. We assessed depressive symptoms using the PHQ-9 (Kroenke et al., 2001).

Analytic Plan

We will begin by examining the distribution and missingness of our outcome of interest, VAS. To take advantage of every available data point and account for repeated measures clustered within individual participants, we will run mixed-effect models in {STATA/SAS/R}, using a nested model-building process. If VAS is normally-distributed, we will specify linear mixed-effects models; otherwise, we may need to transform or dichotomize the outcome to ensure model assumptions are met. We will first run a simple model with only time (0, 6, 12, 18 weeks) as a Level I fixed effect predictor and VAS as a dependent variable, with the participant identification number included as a Level II random effect due to intra-individual correlation of VAS over time. Then, we will run increasingly complex models with intervention assignment (Cell Phone Support calls or texts n = 40 versus automated text reminders n = 20) includes as a Level II fixed effect predictor, and then sex assigned at birth, focal medical diagnosis, medication complexity, age, and racial/ethnic identity as Level II fixed effect predictors, as well, to adjust for known or theoretical covariates. I will examine the impact of including increasing number of hypothesized predictors on model fit by examining AIC and R^2, and pare down the model if the model fit does not improve with all the hypothesized predictors including. This will lead to presenting parsimonious models that estimate the independent effect of the intervention on outcomes of interest, adjusted for all other predictors in the models. Finally, I will also assess whether model assumptions were met by plotting residuals versus fitted values. When I am

confident I have developed the most parsimonious, best-fitting model, I will calculate effect size estimates for the average difference in mean VAS between the Cell Phone Support call and text groups (n = 40) and the automated text reminder group (n = 20).

Then, we will follow the sample approach to predicting MEMS Caps adherence outcomes, and depression, social support, and self-efficacy. We will also run exploratory analyses using electronic-health record abstracted values (e.g., immunosuppressant levels, anti-epileptic drug levels, hemoglobin A1C, mean corpuscular volume/fetal hemoglobin) within focal diagnosis groups.

Finally, for exploratory purposes, we will calculate pre-post effect sizes for subgroups of interest to explore whether interventions are comparably efficacious by focal diagnosis, gender, and racial/ethnic identity. Stratification was used to reduce the variation in potential confounders to be spread similarly between conditions, but that is not always entirely successful, especially in a small pilot trial. Therefore, we will conduct exploratory analyses including measured covariates as potential confounders or effect modifiers in the model-building process.

Missing Data Plan

I will evaluate the impact of missing data on my results by re-running these analyses using inverse probably weighting. It is possible that missing data will not be completely at random (i.e., participants with lower medication adherence may also be less likely to adhere to the online survey schedule).

Power Analysis

Using STATA SE Version 15 software, we estimated the statistical power achieved with our proposed sample, assuming the Cohen's d effect size of 0.85 between groups seen in our preliminary data, within-subject intra-class correlation of 0.5 for repeated measures. We used the

design effect for clustered data (3 post-baseline measures, intraclass correlation=0.5) to compute the effective sample size for each group. The table below shows estimated power to detect differences in CPS (combined) versus automated reminders, and for the comparison of CPS strategies (original vs live text) in the total sample and by medical condition. To be more conservative, we also provide the statistical power for the CPS comparisons with a smaller effect size of 0.75 and 0.50. We also computed power to detect simple pre/post (e.g., baseline-12 week) changes between groups. There is approximately 87% statistical power for group comparisons using the combined sample with the effect size of 0.85; power is reduced for subgroup comparisons and the smaller effect size. However, as this study is a pilot randomized trial, the sample is more than sufficient to estimate effect sizes and assess feasibility for use in future proposals. See Table 1 for details.

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