The CoolCraig App:

Promoting Health by Improving Self-Regulation in Adolescents with ADHD

FINAL PROGRESS REPORT

Submitted by Kimberley D. Lakes, Ph.D. (PI), University of California, Riverside

Project Team

Kimberley D. Lakes, Ph.D., Professor, Department of Psychiatry and Neuroscience, University of California, Riverside

Gillian R. Hayes, Ph.D., Kleist Professor of Informatics, Vice Provost for Graduate Education, Dean of the Graduate Division, University of California, Irvine

Sabrina E. B. Schuck, Ph.D., Assistant Professor in Residence, Department of Pediatrics, University of California, Irvine

Franceli Cibrian, Ph.D., Assistant Professor, Fowler School of Engineering, Chapman University

Michele Nelson, MD, Assistant Health Sciences Clinical Professor, Department of Psychiatry, University of California, Riverside

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Federal Project Officer
Steve Bernstein, Ph.D.

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ABSTRACT

Purpose: To address the chronic and pervasive impairments associated with Attention Deficit Hyperactivity Disorder (ADHD), we developed a digital health intervention (DHI) to improve self-regulation among youth with ADHD.

Scope: We developed and piloted a novel technology called CoolCraig, a wearable and connected system that combined a smartwatch, mobile phone app, and web portal to deliver intervention, promote self-regulation, and improve adherence to treatment over time for youth with ADHD.

Methods: Our first aim was to establish key design principles and implement these principles in the CoolCraig system. We conducted a series of design workshops with 40 participants (children/adolescents, parents, teachers, clinicians) to develop a wearable, context-aware system for supporting long-term cognitive behavioral change. Our second aim was to evaluate the feasibility and acceptability of the DHI. We recruited two cohorts for a total of 20 youth with ADHD for a pilot intervention study.

Results: Our work on this R21 has already resulted in 12 publications. Results described in those papers address the importance of balancing self- with co-regulation for children with ADHD and how this can be reflected in DHI. Results also illustrated how DHI supported self-regulation during periods of pandemic-related distance learning, which were particularly difficult for children with ADHD. Our work yielded guidelines—from multiple (child, parent, teacher, clinician) viewpoints—for designing technological interventions supporting children with ADHD. Our results demonstrated feasibility and identified DHI features that users found most useful. We gained a better understanding of how children visualize and understand their data, which led to revisions in our prototype and plans for an expanded DHI for future research.

Key Words: ADHD, digital health intervention, self-regulation

1. PURPOSE

Given the chronic and pervasive impairments associated with Attention Deficit Hyperactivity Disorder (ADHD), high rates of child comorbidity, and heightened problems in child social interactions and relationships,[1] children with ADHD are at risk for poor outcomes[2] and require intensive interventions, such as behavioral training programs. These programs are periodically followed by brief interventions to ensure maintenance of treatment progress. Despite substantial success in clinical interventions, long-term adherence can be challenging. Moreover, as children with ADHD become adolescents, it is common for them to receive less frequent treatment and support in spite of the fact that they face increasingly difficult situations in academic (high school curriculum) and social (exposure to drugs, alcohol) settings. Recent research has shown that adolescents with persistent ADHD are more likely to engage in serious risk behaviors, such as underage drinking, reckless driving, and illegal drug use.[3] Research has shown that self-regulation is a robust predictor of positive outcomes in adulthood and that early adolescence is a critical period for promoting self-regulation to prevent life-altering mistakes, which often have their roots in the high school years.[4]

Wearable computing and the Internet of Things have made truly low-cost, highly customized interventions possible and are expected to take giant leaps in the next ten years.[5,6,7] These approaches provide innovative mechanisms for delivering long-term follow-up interventions that enhance and reinforce treatment. This project was designed to develop and pilot a novel technology called CoolCraig, a wearable and connected system that combined a smartwatch, mobile phone app, and web portal to deliver intervention and improve adherence to treatment over time for youth with ADHD.

To address the complex behavioral and mental health needs of adolescents coping with ADHD and to contribute to scientific knowledge about improving treatment adherence and outcomes, this pilot project was designed to adapt a technological intervention in a way that would easily translate to a subsequent pragmatic clinical trial. CoolCraig was informed by social cognitive theory,[8] as it 1) puts health knowledge into patients' hands in a way that is easy and quick to access; 2) helps patients set goals and receive prompts related to their goals; 3) prompts patients to reflect on their successes, thereby building self-efficacy and the expectation that their behavior is modifiable; 4) helps patients evaluate their progress, promoting self-regulation; and 5) addresses barriers to change such as lack of consistency implementing recommended strategies. Our project was designed to address two primary aims as well as to gather data for future research.

2. SCOPE

Attention Deficit Hyperactivity Disorder (ADHD) is the most prevalent childhood psychiatric condition, affecting nearly 1 in 10 children in the United States,[9] with a profound public health, personal, and family impact. Recent estimates put the annual cost of ADHD as high as $266 billion, much of which is lost productivity and income for adults with ADHD and parents of children with ADHD.[10] ADHD requires comprehensive treatment, including child interventions (e.g., behavioral treatment, medication), parent training, and educational planning. Because ADHD is chronic and lifelong, maintenance, which requires substantial self-regulation, is needed to support initial treatment gains.[11] Our aim was to enhance self-regulation and self-efficacy by prompting youth to implement therapeutic strategies and to reflect on their progress. Traditional methods of intervention cannot address this need. Paper and electronic mailers are likely to be discarded,[12] and in-person therapy with a clinician does not scale over the long-term for every individual (particularly as adolescents often phase out of therapy, especially as they transition to college or independent living) and is very costly.

Our overarching goal was to study how new technologies could be used to enhance and maintain treatment gains and to provide best practices for collecting, reflecting, and intervening on personal health information related to behavioral challenges. In 2015, 73% of adolescents in the U.S. had access to a smartphone, numbers that are only expected to rise.[13] Additionally, these gains may be felt even more profoundly by those most under-served by the existing healthcare system; low-income, youth, and minority status are all indicators of a greater likelihood of use of mobile phones for Internet access than more traditional methods.[14] Notably, researchers who focus on teens and mental health note that for the most part, access to these smartphone technologies are relatively positive, regardless of what some limited studies picked up by the media might argue.[15]

Smartphones can run sophisticated applications to record and analyze data and deliver educational messages to patients. Cell-phone reminders improve attendance at outpatient appointments[16,17] and improve adherence.[18,19,20] By coupling near-ubiquitous smartphones with off the shelf wearable technologies (e.g., fitness trackers), we can offer a sophisticated yet highly available alternative to existing, failing approaches to long-term maintenance. Although still a relatively small market compared to mobile phone penetration, wearables are increasingly a part of everyday life, particularly amongst younger people. Deloitte's global mobile survey indicated that 23% of Americans own a fitness band and 13% own a smartwatch.[21] Major insurance companies have begun to prescribe and pay for smartwatches for long-term health management.[22] Our approach aimed to ensure that the significant investment in mental health treatment is not squandered by a failure to follow up over time. Instead, adolescents should get the interventions they need when they need them leading to long-term positive outcomes in individuals and society at large. A key factor in the success of health technologies is whether they are perceived to meet real needs and expectations.[23,24] Technological solutions are particularly supportive to those who are **under-resourced or non-native English speakers**.[25] However, technologies must adapt to varying practices surrounding health technologies across individuals and over time. For example, two adolescents with ADHD might have very different health technology needs and practices.

In summary, long-term maintenance of intervention gains is challenging, particularly as adolescents enter a stage of independence and transition out of their parents' homes. Innovative technologies can bridge this gap. Little research has characterized how adolescents conceive of and apply lessons from treatment long-term nor how they might best be prompted to manage their condition. Additionally, research has not yet addressed how mobile and wearable technology needs and practices differ for adolescents and how this might influence the design and development of personal health technologies. Better modeling of these constructs will bolster the design of systems to promote self-management.

The goal of this funded study was to develop the CoolCraig system, informed by this theory and best practices in ADHD treatment. First, providing treatment recommendations on a user-friendly app puts health knowledge into adolescents' hands in a way that is easy and quick to access. Second, the system was designed to help adolescents set goals, receive prompts to utilize strategies to achieve those goals, and reflect on their successes (building self-efficacy and the expectation that their behavior can change). These goals could be set in multiple domains, customized to the treatment plan. In addition to behavioral goals (e.g., completion of homework, compliance with parent or school rules), goals could address hours of sleep per night, amount of physical activity during the day, and compliance with a medication regimen. Once goals are set, participants were able to track their progress daily and weekly in each of the target domains. The use of goal-setting and weekly review of and updating personal goals was hypothesized to promote self-regulation; in addition, it could provide data to be shared with parents and the patient's clinician(s) regarding progress meeting treatment goals.

In our clinical practice and research with children with ADHD, common barriers to change include lack of consistency implementing strategies and forgetting to use strategies, both of which were addressed by the app. CoolCraig provided an appealing, low-cost, sustainable intervention that could reinforce positive health behaviors for long periods of time. Our participatory design work aimed to ensure that this theoretically driven system would also be useful, usable, and enjoyable for youth with ADHD.

Improving self-regulatory skills involves targeting information to an individual's context. This kind of targeting is only possible by modeling the context during which people receive health information, including their physiological and mental states and the surrounding environment. These models do not yet exist, and their development would be a substantial contribution to both behavioral science and computing research. Clinicians generally rely on clients to self-report on these dimensions, which can be unreliable. Thus, alongside the self-report data collected through CoolCraig's interface, we also automatically collected sensor data for creating machine-based models of patient context, such as time of day, physical activity, sleep disturbances, and social activity.

3. METHODS

Aim 1: To Establish Key Design Principles and Implement These in CoolCraig. Our first aim was to establish key design principles for the support of adolescents with ADHD and implement these principles in the CoolCraig system. We conducted design workshops with four cohorts of 4 to 6 participants each over five weeks, as is best practice in cooperative design. Because CoolCraig aimed to support multi-modal intervention with adolescents, groups included parents, clinicians, and youth with ADHD. Groups were provided with specific prompts or cues toward a key issue identified in our preliminary work. For example, one group focused on designing for adolescents rather than adults, while another group focused on distributing data collection and aggregation. These groups identified similar opportunities, concerns, and designs; however, by using design-based activities to explicitly cue particular issues, we gained additional insight into how technologies might support those aspects.

Groups met once per week for one to two hours over the course of multiple weeks, with our research team working in between to iterate on prototypes, working toward a functional system. We analyzed the results of early workshops to develop personas and scenarios of use that we then fed into subsequent workshops as well as our final design guidelines. Between workshop sessions, the research team developed prototypes—paper and narrative based at first, functional towards the end—to continue to seed the discussions. We used the final workshop to validate and modify a draft set of design guidelines.

With cooperative design, we finalized the requirements, user experience, and details of the hardware and software to inform the design and functionality of the CoolCraig system. CoolCraig, a wearable, context-aware system for supporting long-term change, included three core modules: educational information, data collection, and data visualization.

Aim 2: To Evaluate the Impact of CoolCraig, a Novel Wearable, Mobile, and Connected System. We evaluated the feasibility and acceptability of CoolCraig in a pilot deployment study, and we gathered data to inform further refinement of CoolCraig as well as to develop a protocol for a future clinical trial.

Participants. Our goal was to recruit 20 children/adolescents with ADHD. At least one of the participant's parents or legal caregivers was required to enroll in the study.

Procedure. Participants used CoolCraig to reinforce, extend, and maintain treatment gains. We provided smartwatches for the child and loaned smartphones to their parent when the parent did not have a smartphone that could be paired with the child's smartwatch. Whether using our phone or their own, all participants were taught basic cybersecurity and privacy best practices, including how to lock and encrypt phone data.

Participants were assessed four times: Baseline (prior to the start of intervention), midway through the intervention, following the conclusion of the intervention, and a subsequent follow-up. At each assessment, researchers interviewed participants, parents, and clinicians, and outcome measures were administered. Assessments were conducted virtually in light of pandemic restrictions and included remote administration of assessment measures and videoconferencing.

***Quantitative Data Analyses*.** We collected quantitative data from participants using well-validated research measures and the CoolCraig system itself. In this way, we examined phenomenon and worked to create robust models for self-regulation, response to various contextual cues, and the feasibility, acceptance, and potential impact of our approach. Quantitative data from outcome measures was collected to examine both proximal and distal outcomes in a longitudinal repeated measures design. Measures assessed primary outcomes (self-regulation and self-efficacy) and secondary outcomes (e.g., ADHD symptoms). CoolCraig asked youth to record daily challenges and triggers as well as to answer questions about the appropriateness of the system, their response to the system, and their state of mind at the moment of a reminder. Alongside these self-reported data (which were used to examine adherence and use of the app), CoolCraig itself collected automatically sensed contextual data (e.g., heart rate, sleep patterns, physical activity). This procedure created several hundred high-quality feature vectors per day per user.

We acknowledged from the start that this was a pilot study; we did not expect to have sufficient power to detect statistically significant improvements at this stage. However, we analyzed the data collected to evaluate the utility of the selected measures, feasibility and acceptability of the DHI, and to pilot test the analytical procedures for a subsequent clinical trial.

Qualitative Data Analyses. To evaluate the feasibility and acceptability of CoolCraig and the study protocol, we employed observational and interview-based research methods to develop a rich understanding of the everyday experience of participants, parents, and clinicians engaging with this novel technology. These methods are a leading technique for investigating technological settings in human-computer interaction research and are useful for examining complex settings where technical, behavioral, and social factors intersect. Using an iterative cycle of observation and analysis, we examined user experience to guide the development of a future system.

Interviews were recorded and transcribed verbatim. Study team members conducting interviews and observations recorded: a) descriptive notes after each period of observation, and b) analytic memos with descriptive notes and interview transcripts. Researchers talked with participants and their parents regularly throughout the study, as a method for collecting additional empirical data about their experiences as well as to support their use of the technologies and to promote engagement in the intervention and research study. Our analysis was guided by Grounded Theory,[27] in which data collection, data analysis, and theory development occur continuously, and each activity overlaps and informs the others. One of the hallmarks of this approach is that as researchers begin to form categories in the data, a process of constant comparison begins and all new pieces of information are held up against those that already populate the category; in this way, researchers are pushed to challenge and refine their descriptions.

4. RESULTS

We successfully met our specific aims and study milestones, which are summarized below for each of the study aims.

Specific Aim 1: *To establish key design principles for the support of adolescents with ADHD and implement these principles in the CoolCraig system.*

- We recruited 24 children (ages 10-13) and 8 teachers and 8 parents to participate in design sessions. Our full Aim 1 recruitment goal was 24 participants, consisting of children, teachers, parents, and clinicians. The total number of participants completing design sessions was 40, which represents 167% of our recruitment goal.
- We conducted 14 design sessions and developed provisional scenarios, which were presented and discussed in the sessions.
- We analyzed the data, created design principles, and developed a prototype system for CoolCraig, a digital health intervention (DHI). During the participatory design workshops, children discussed topics related to wearable technology, self-regulation strategies, or potential features for a smartwatch application, followed by a sketching activity where children used paper prototypes. During focus groups and interviews with the caregivers, we studied opportunities to design a smartwatch application supporting self-regulation at home. Our results highlighted the importance of balancing self- with co-regulation for children with ADHD and how this can be reflected in the DHI. Our work yielded guidelines—from multiple (child, parent, teacher, clinician) viewpoints—for designing technological interventions supporting children with ADHD.

- Please see publications 1-8 in our list of grant-supported publications for papers resulting from this work. During this time, we also conducted an extensive review of DHI in ADHD research to further inform our efforts.

Specific Aim 2: *To evaluate the feasibility and acceptability of CoolCraig in a pilot study.*

- In March 2020, we were scheduled to begin the feasibility and acceptability trial for our DHI. Within days, California's governor issued a stay-at-home order in response to COVID-19. Recognizing that the stay-at-home order presented new significant stressors for children with ADHD and their families, we rapidly adapted our work to study how DHI might support mental health treatment and educational participation during COVID-related stay-at-home orders**.** The COVID-19 crisis was projected to be challenging for youth with ADHD due in part to their difficulties with organization and increased risk of not participating in scheduled online learning. Thus, we added features to our prototype, such as personalized calendars with each participant's daily distance learning schedule to help address the new challenges children and parents would face. This approach supported home learning by providing reminders, easing the burden on parents, and potentially reducing the parent-child conflict associated with frequent reminders and struggles over task completion.
- We began the first cohort of our pilot trial in the Spring of 2020 using a protocol that included plans for remote consenting, remote mental health assessment, and Zoom participant interviews. We established a no-contact protocol to deliver Apple Watches (for the child) and paired iPhones (for the parent) to participant homes. Ten children and their caregivers consented to participation in this first cohort. We gathered data from the Apple Watches to study physical activity and sleep patterns and to work with participants to set goals for healthy routines. We tested a prototype system and collected mental health outcomes data using remote psychological assessments of mental health symptoms (e.g., ADHD, depression, anxiety).
- This pilot study led to additional papers that demonstrate that the novelty effects of wearing a smartwatch last less than a week in these children, and that most of the children were able to wear, charge and use the Apple Watch on a daily basis for 6 weeks or more. Feedback from participants indicated that they viewed the DHI as particularly useful in supporting routines, including participation in distance learning.
- We continued the pilot study, recruiting a second cohort to meet our Aim 2 goal of piloting the DHI with a total of 20 youth. Using iterative development, we studied an improved version of the DHI, with components for participants and their caregivers.
- This work demonstrated the utility of schedule and task notifications as well as the potential for the technology to deliver timely intervention and to increase adherence to treatment recommendations. We also gained a better understanding of how children visualize and understand their data, which led to revisions in our prototype; data from the final round of the pilot study are currently in preparation for publication.
- See publications 9-12 in our list of grant-supported publications for papers resulting from this phase of our work. During this time, we also conducted reviews of DHI for ADHD targeting specific domains of functioning to further inform our efforts.

5. LIST OF PUBLICATIONS SUPPORTED BY THIS GRANT

To date, our work on this R21 has yielded 12 publications: 11 published peer-reviewed journal articles and 1 peer-reviewed scientific book (*denotes a trainee co-author) in addition to a prototype digital health intervention. Three additional articles under review are not listed below.

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10. Cibrian, F., Monteiro, E.,* Ankrah, E.,* Tavakoulnia, A.,* Beltran, J.,* Schuck, S., Hayes, G.R., & Lakes, K.D. (2021). Parents' Perspectives on a Smartwatch

Intervention for Children with ADHD: Rapid Deployment and Feasibility Evaluation of a Pilot Intervention to Support Distance Learning During COVID-19. *PLOS ONE.*

11. Cibrian, F.,* Lakes, K.D., Schuck, S., & Hayes, G. (In Press). The potential impact of technologies supporting self-regulation in children with ADHD: A literature review. *International Journal of Child-Computer Interaction.*

12. Lakes, K.D., Cibrian, F.,* Schuck, S., Nelson, M., & Hayes, G. (In Press). Digital health interventions for youth with ADHD: A mapping review. *Computers in Human Behavior Reports.*

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