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Feasibility of pediatric obesity and prediabetes treatment support through Tess, the AI behavioral coaching chatbot

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Cite this as: *TBM* 2019;9:440–447 doi: 10.1093/tbm/ibz043

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Abstract

Behavioral intervention technologies (BITs) are unique ways to incorporate the benefits of technology and psychology to address differing health needs through various media, including Internet interventions, mobile apps, and video games. BITs present several possible benefits, including increased dissemination and accessibility, cost-effectiveness, increased engagement, and decreased stigma, especially among youth. A behavioral coaching chatbot, Tess, addresses different facets of behavioral health, such as depression and anxiety. Available 24/7. Tess delivers customized integrative support. psychoeducation, and interventions through brief conversations via existing communication channels (i.e., SMS text messaging and Facebook Messenger). This study assessed the feasibility of integrating Tess in behavioral counseling of adolescent patients $(n = 23; M_{300} = 15.20 \text{ years}; \text{Range}_{300} = 9.78 - 18.54 \text{ years};$ 57% female) coping with weight management and prediabetes symptoms. Tess engaged patients via a preferred method of communication (SMS text messaging) in individualized conversations to promote treatment adherence, behavior change, and overall wellness. Adolescent patients reported experiencing positive progress toward their goals 81% of the time. The 4,123 messages exchanged and patients' reported usefulness ratings (96% of the time) illustrate that adolescents engaged with and viewed this chatbot as helpful. These results highlight the feasibility and benefit of support through artificial intelligence, specifically in a pediatric setting, which could be scaled to serve larger groups of patients. As a partner to clinicians, Tess can continue the therapeutic interaction outside office hours while maintaining patient satisfaction. Due to Tess's capacity for continuous learning, future iterations may have additional features to increase the user experience.

Keywords

Artificial intelligence, Chatbot, Behavioral intervention technologies, Diabetes, Obesity, Pediatric

Pediatric obesity has been a well-documented and growing health concern in the USA, reportedly impacting 17% of school-aged youth (6–11 years old) and 20.5% of adolescents (12–19 years old) [1]. Further, these youth commonly demonstrate signs of developing diabetes as a comorbid condition. Signs and symptoms associated with prediabetes include acanthosis nigricans, elevated hemoglobin A1c, and other findings related to insulin resistance [2]. Beyond these physical health concerns, like the potential for diabetes and hypertension, these youth

Implications

Practice: Support from an artificial intelligence behavioral coaching chatbot is feasible and reported useful among youth enrolled in a weight management program.

Policy: Policymakers who want to aid in the reduction of obesity and diabetes among youth should explore scalable and attractive tech-based interventions, like this artificial intelligence behavioral coaching chatbot, to support behavioral counseling treatment and weight management programs.

Research: Future research should be aimed at identifying the most useful and impactful components of the chatbot support, testing novel features, and enhancing the user experience.

often endure negative psychological symptoms as well, such as low self-esteem and self-image, which may also increase their likelihood of manifesting psychological disorders like depression [3,4]. Additionally, overweight and obesity problems experienced during childhood often continue into adulthood, with overweight adolescents having about a 70% likelihood of being overweight as an adult [5]. These findings point to the crucial need for effective interventions that support lifestyle modifications aimed at treating obesity in children and adolescents.

Currently, treating childhood obesity is designed to be delivered in a four-tier model, as recommended by an Expert Committee convened through the American Medical Association [6]. With each tier aimed at progressively increasing the level of support, the four suggested tiers are: prevention, structured weight management, multidisciplinary treatment, followed by tertiary care. Access to the higher tier levels of care is limited within this four-tier model. Despite evidence suggesting that the best results are due to a multidisciplinary team approach, a survey of 114 children's hospitals across the USA revealed that one-third (31%) of them does not offer the comprehensive, stage 3 care [6,7]. Preferred multidisciplinary care services are limited in regions

even with children's hospitals and potentially nearly nonexistent in regions without children's hospitals [6,8].

Treatment impacts not only the patients but also the families, treatment providers, and society, such as attrition, burnout, or costs. As advised by the Expert Committee [6] and the U.S. Preventive Services Task Force [9], children with obesity and their families should be provided lifestyle behavioral counseling. Weight management programs providing lifestyle behavioral treatments exceeding 26 contact hours demonstrate some clinical effect, with programs exceeding 52 contact hours producing significant change in BMI z-scores [9,10]. The challenge with behavioral therapy is that a relatively high dose of the intervention (≥14 sessions) is required to yield an observed change [10,11]. Patient retention with weight management programs have been challenging, where attrition rates are significant with studies reporting greater than 50% drop out [12,13]. Two of the top reasons parents withdrew their children from a third tier program were due to time conflicts (50%) or the lack of program flexibility (33%) [12]. It has been pointed out that treatment for overweight difficulties and obesity during childhood rarely exist in isolation, with other family members potentially experiencing similar difficulties and/ or a large amount of responsibility falling on the parent(s)/guardian(s) to implement necessary lifestyle changes [8]. Additionally, treatment and care for children with obesity often requires a substantial commitment from the family, involving missed school/work days, logistical difficulties around distance and transportation, as well as the financial burden of copayments and unreimbursed expenses, which could include dietitian visits and enrollment in fitness activities [14-16]. Parents may have to balance the long-term benefit of committing to their child's treatment and the immediate costs. Beyond the burden on the families, childhood overweight and obesity problems extend to larger societal costs, estimated around \$14 billion annually, which only increases as these youth become adults [7,17]. Many patients experience general barriers to treatment, including financial strain and logistical difficulties like transportation [18,19]. These barriers may be amplified among youth populations, particularly "buy-in," engagement in, or stigma related to treatment [20]. Moreover, pediatric settings have been documented as fast-paced settings that may offer time-limited support services [21]. Technology services have the potential to offer unique tools that can be utilized to help reduce these barriers, both for consumers and society as a whole.

Behavioral intervention technologies (BITs) are novel solutions that incorporate the benefits of technology and psychology to address differing health needs through various media, including Internet interventions, mobile apps, and video

games [18]. BITs present many benefits, including increased dissemination and accessibility, costeffectiveness, increased engagement, and decreased stigma, especially among youth. Additionally, BITs may aid in increasing patient autonomy and rapidly streamlining the process of generating improvements to existing treatments (compared to traditional face-to-face [FTF] studies) [21]. Similarly, BITs may enable researchers and clinicians to optimize, tailor, and improve the interventions based on patient feedback and data gathered. Unlike traditional psychotherapy treatments, most BITs require a limited level of human support and can be considered "nonconsumable" (i.e., use of a BIT by a person does not "use up" the intervention and does not prevent its use by others) and scalable (i.e., the more users, the lower the marginal cost of administration with no loss of therapeutic potency) [22]. The "nonconsumable" and scalable nature of BITs may be particularly beneficial in pediatric medical settings.

Artificial Intelligence (AI) is one of the more recent, burgeoning forms of BITs that is being utilized for behavioral and mental health [23]. Examples of existing mental health AI solutions include a cognitive behavioral therapy (CBT) based conversational agent, Woebot, and one of the original natural-language processing programs, ELIZA [24,25]. This study examined one psychological AI service, Tess, which has been used to address different facets of mental health, such as depression and anxiety [26]. Available 24/7, Tess delivers customized, integrative support, psychoeducation, and interventions through brief conversations via existing communication channels (i.e., SMS text messaging and Facebook Messenger).

The purpose of this manuscript is to gain a better understanding of the feasibility of a textbased AI service (Tess) as an adjunct to existing treatment, specifically for pediatric practice of weight management and prediabetes counseling. Tess may be able to provide an extension of the office visit, where work done between the clinician and patient can be reinforced and reiterated $\vec{\otimes}$ through targeted interventions that are tailored $\leq \frac{1}{20}$ to the patient in between sessions. While other interventions may exist that provide standardized $\frac{2}{10}$ messages or reminders (e.g., "Don't forget to take your medication today"), Tess is designed to provide conversations that are personal and on-demand for the individual. Virtual AI assistants may help support adherence to existing treatment methods. Furthermore, within the four-tiered approach for pediatric weight management, obesity treatment, and prediabetes intervention, BITs like Tess may be uniquely able to build capacity across the tiers. We propose that BITs are a possible solution to the existing challenges with obesity treatment for patients, families, and providers. Further, we posit

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BITs can overcome the high rates of treatment attrition, despite evidence that lifestyle behavioral counseling contact hours are predictive of treatment success.

METHODS

Participants

Twenty-three youth with obesity symptoms who were enrolled in a multidisciplinary weight management program at a children's healthcare system were recruited as a convenience sample for this feasibility study. Participation in the weight management program (not the study) required BMIs ≥95% for age and sex. All patients had at least one comorbid condition including acanthosis nigricans and/or elevated hemoglobin A1c, suggesting risk for diabetes, hypertension, dyslipidemia, or obstructive sleep apnea. Due to the small sample size, limited demographic characteristics are reported in order to protect patient confidentiality. Approval to conduct this study was obtained from the Nemours Children's Hospital Institutional Review Board (#980585).

Intervention

This study examined a behavioral coaching chatbot service ("Tess") designed by X2AI, that delivers brief text-based interventions with a novel integrated therapeutic approach. Many BITs in the field are based on CBT, which is why the integrative approach is one aspect that makes Tess unique. Tess is intended to serve as an adjunct to treatment, in an attempt to extend support beyond the office. This chatbot service engages users in on-demand, convenient, and personal conversations through convenient communication channels (i.e., SMS text message, Slack, WhatsApp or Facebook Messenger); SMS text messaging was utilized in this study. As a commercially available service, Tess is equipped with a customizable platform where the content can be tailored for specific populations or interventions. For this study, the system was customized through a collaboration between X2AI and Nemours Children's Hospital for a weight management program for youth dealing with obesity and/or prediabetes. Tess integrated the intensive behavioral counseling recommended for weight management programs for obesity, paired with mental health approaches that are well suited to support behavior change (e.g., motivational interviewing, behavioral activation, and CBT).

Technical and customization features

Tess functions through a combination of technologies, algorithms, and machine-learning strategies that enables a range of features that are customizable. One particularly distinguishing aspect of Tess's technology is the emotion algorithm that

enables analyzation of the incoming messages from users based on the emotions expressed [27]. Patients can access Tess through a text-capable mobile phone number or an existing account, like FB Messenger or WhatsApp, without needing to download a separate "Tess" app. These conversations can also be held by speaking out loud, as Tess is integrated with Google Home and Amazon Alexa. Tess delivers evidence-based interventions rooted in a variety of psychological theories and modalities, such as CBT, emotionally focused therapy, or motivational interviewing. Tess is designed to reply to users with scripted statements that have been crafted and reviewed by mental health professionals in an effort to mimic empathy and compassion. Similar to how therapists may adjust their style or modality to address each client's needs, Tess delivers interventions and responds based on the individual's reported emotion or concern. Tess also asks for feedback in order to deliver more personalized support (e.g., adjusting interventions provided based on level of self-reported usefulness). Tess learns from every interaction on an individual and group level. After each intervention, Tess asks the user if the suggestions provided were helpful. If yes, then Tess will deliver interventions that align with that topic or modality. If no, Tess will try something different to give the user alternative intervention options.

The administration panel used to customize Tess may be integrated with existing electronic health record (EHR) systems for more efficient patient management. Tess integration within existing EHR systems is capable of the data Tess gathered auto-populating directly into the system without requiring extra work of the physician. Access to the administration panel is restricted with unique log in credentials that can be assigned to different levels such as admin, supervisor, and practitioner. Data processing and storage are on secure servers that satisfy Health Insurance Portability and Accountability Act (HIPAA) regulations and within the country of residence for all participants given access.

Nemours Children's Hospital compiled 5 years of documented patient-targeted behavior changes (e.g., goal = be ballerina, targets for goal = practice dance for 1 hr on Monday, Wednesday, and Friday). This set of targeted behavior changes was then de-identified and shared with X2AI to develop the clinical scripts, where the pediatrician/physician responses were converted into a form that Tess could deliver. An internal review process was conducted by both X2AI and Nemours Children's Hospital in a tiered approach, where three X2AI members (a mental health consultant, an AI writer, and a software tech engineer/AI trainer) reviewed the scripts and then allowed the physician and health coaches to test interacting with Tess. The physician and health coaches provided feedback,

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which yielded multiple iterations and the resulting final product used for this study.

Measures

The usability of Tess is measured using some common technology-based intervention metrics, such as engagement levels and helpfulness as well as more behavioral metrics including progress toward goals.

Engagement

Engagement was measured based on the duration of conversations patients had with Tess (i.e., longest, shortest, and average).

Exchanges

Total quantity of messages exchanged with Tess, which compiled creates the amount of conversations held with Tess. Total number of hours of Tess support exchanged and percentage of exchanges outside of typical office hours (8 am to 5 pm).

Helpfulness

Patient self-reported endorsement of Tess's helpfulness during conversation (e.g., "Was that helpful?").

Initiation

Ratio of Tess-initiated versus patient-initiated conversations.

Target goal progress

Percentage of patients' self-reported progress toward the clinician-inputted target goals that were addressed through conversing with Tess.

Procedure

As a feasibility study, the AI behavioral coaching chatbot, Tess, was assessed for potential to improve the quality of care delivered in the existing weight management program through the Nemours Children's Hospital. Prior to this study, the multidisciplinary team had already implemented unidirectional text messaging, which delivers scheduled individualized reminders to patients based on negotiated targeted behavioral changes (e.g., "Keep up the good habit of eating fruits and vegetables with each meal and as your snack" and "Way to go with practicing basketball"). Therefore this project aimed to investigate Tess as a more on-demand, accessible, convenient, and integrative extension of the text-based program already in place.

Rolling recruitment was conducted across 6 months (chosen a priori). Through the weight management program, study subjects received lifestyle behavioral counseling and goal setting with their physician. Specific goals (e.g., "I will be a great basketball player" and "I'll be comfortable

in my red outfit") and targeted behaviors (e.g., "I will eat my healthy plate at dinner" and "I will practice basketball after school for 30 minutes on Monday, Wednesday, and Saturday") were then entered into a customized Tess portal. Tess was then able to interact with the patients surrounding their individualized goals-both in Tess-automated or patient-initiated conversations. Average patient exposure to Tess lasted approximately 10-12 weeks based on the time of recruitment and active status in the weight management program. Screening of these conversations, by both the specialty physician and a mental health consultant/AI specialist, was conducted to ensure the conversations were actually occurring, as well as quality improvement logistics (e.g., chatbot was interacting properly). Conversations were screened three times per week during the first 2 weeks and once per week during the following weeks. Approximately 5% of human intervention was applied for quality assurance during the early stages of this study, whereby X2AI received alerts that the conversation needed support (e.g., system error or received "no" answer to a question) and a member of the X2AI team would take over the conversation until it was corrected and Tess could resume. One change implemented due to human intervention was to reduce interventions focused on negative emotions and increase interventions focused on positive emotions.

Engagement rates were also assessed during these review procedures in order to examine the numbers of messages exchanged and frequency at which the patients interacted with Tess (both self-initiated and Tess-initiated conversations). This enabled minor adjustments to the frequency at which Tess reached out in order increase engagement, if necessary.

Statistical analyses

Frequencies and descriptive statistics were conducted to analyze the participant baseline demographic information and the usability metrics. Qualitative themes were gleaned from the dialogue recorded in the text message exchanges between Tess and the patients by the clinical X2AI team member.

RESULTS

Participant demographic results are in Table 1. Mean patient age was 15.20 years with a range spanning 9.78–18.54 years at the time of recruitment. A majority of the sample was Hispanic (43%) or White (39%) and 57% was female.

Table 2 presents the engagement, helpfulness, and initiation metrics. A total of 4,123 messages were exchanged between participants and Tess, resulting in about 269 total conversations (with \leq 30 min of inactivity) and averaging about 12 conversations per patient (standard deviation [SD] = \pm 8.84). The longest conversation between Tess and a teen patient was 1 hr and 13 min long,

n (%)
13 (57%)
10 (43%)
1 (0.43%)
2 (0.87%)
1 (0.43%)
3 (1.3%)
2 (0.87%)
3 (1.3%)
5 (2.2%)
4 (1.7%)
2 (0.87%)
10 (43%)
9 (39%)
2 (9%)
2 (9%)

while the shortest conversations fell between 4 and 7 s. The average duration of conversations between Tess and patients was approximately $12.5 \text{ min } (SD = \pm 15.62 \text{ min})$. The median length of conversations was nearly 6 min (00:05:56; Interquartile Range (IQR) = 00:01:54-00:17:32). Overall, Tess provided about 55 hr and 45 min of support for the adolescent patients, 17.8% of which was provided outside of typical office hours (8 am to 5 pm). A majority of the conversations were Tess initiated (73.6%) compared to patient initiated. Adolescent patients reported experiencing positive progress toward their goals and targeted behaviors 81% of the time (e.g., response to Tess-initiated question of "Have you made progress this week towards your goal of ____?"). Patients indicated that Tess was helpful 96% of the time. Two case vignettes are provided below to illustrate specific experiences.

A 14-year-old boy exchanged 425 messages with Tess. He reported finding conversations with Tess helpful 100% of the time and reported positive progress toward his goals 83% of the time he spent engaging with Tess. This patient indicated feeling comfortable sharing with Tess when he was not feeling well and seemed to quickly and easily engage in the conversations. His engagement levels with Tess fell within the top 5% of the sample, which was notable given his reserved nature during FTF sessions.

Α 15-year-old female patient exchanged 375 messages with Tess and indicated these conversations were helpful 100% of the time. She reportedly experienced positive progress toward her goals 80% of the time she spent engaging with Tess.

This patient connected with Tess over topics like cooking, a healthy diet, and expressing creativity via drawing.

DISCUSSION

Adolescents in a weight management program interacted with Tess and rated their conversations useful, suggesting that this AI chatbot is feasible as an adjunct to treatment. The large number of messages exchanged between Tess and the teens, combined $\ \ \ \ \ \ \$ with the high helpfulness ratings illustrate that this chatbot service may be an influential and engaging support tool for youth. Conversations varied in length, with some as short as a few seconds to longer than an hour, which differs from usual treatment that has a set, prescribed duration. The observed average number of conversations exchanged $(M = 12; SD = \pm 8.84)$ is relatively consistent with other conversational agents, such as the Woebot where users checked-in with the bot on average 12.14 times [24].

As mentioned, Tess was explored as a potential more personalized and conversational expansion of the existing text message program at Nemours Children's Hospital. X2AI determined that it takes approximately 2 min per message for an individual clinician to read, draft a response, and wait for a reply. Based on this and average hourly clinician fees, the observed engagement between Tess and the patients could be estimated to equate 137 hr if done by a staff member and may have saved approximately \$8,933. Moreover, traditional FTF therapy often requires the hourly salary clinician, overhead costs of the clinician's office space, and travel time for the employee. Telehealth therapy requires those same three aspects as FTF therapy and yet is on-demand and sometimes 24/7. AI chatbots, such as the behavioral coaching Tess in this study, similarly require the aforementioned three core aspects and yet offers the on-demand, always 24/7 support and the benefit that scaling up does not require more clinicians (which would increase costs). Furthermore, the adolescents were able to continue conversations when most convenient, even with periods of inactivity (i.e., able to pick up conversation where last left off), which would not be possible with a typical provider and their time-limited schedules. The two vignettes $\vec{\phi}$ showcase that Tess is not only capable of connecting with individual patients through their interests but may also be a method through which more reserved teen patients feel more comfortable sharing. These results highlight the beneficial impact Tess could have for patients, particularly in pediatric settings, which could be scaled to reach and serve much larger samples.

Tess may also be a partner for professionals to aid in burnout reduction while delivering more patient support. Future iterations of Tess may implement additional features to increase the

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Table 2 Exchanges, engagement, and initiation re	esults	
Variable	Total	M (SD)
Exchanges		
Messages exchanged	4,123	_
Conversations	269	14.25 (27.58)
Total Tess support hours	55:44:55	_
Exchanges outside office hours	48	_
Engagement		
Shortest conversation length	00:00:03	
Longest conversation length	01:13:04	
Average conversation length		00:12:31 (00:15:37)
Median conversation length	00:05:56	
Interquartile range	00:01:54 - 00:17:32	_
Initiation		
Tess-initiated conversations	198	
Patient-initiated conversations	71	_
SD standard deviation.		

user experience and attempt to support other members involved in treatment (e.g., parents, treatment providers). This study explored the use of Tess in adolescents with obesity in a third tier weight management program. Future work could examine its use in an earlier stage of treatment and perhaps even in prevention. Follow-up studies may also be conducted to assess Tess's support for these individuals, such as diet planning for parents or burnout coping skills for treatment providers. Furthermore, Tess could be more intimately integrated within benefit packages or employee assistance programs to support staff in a customized manner to the setting, like compassion fatigue reduction among treatment providers [28, 29].

STRENGTHS AND LIMITATIONS

AI support from Tess was feasible and helpful within a weight management program for children and adolescents. The collaborative work between Tess and the physicians aimed to best meet the patients' needs, as Tess picked up the conversation where it last left off in the office. Patients continued to receive multidisciplinary care from the weight management program team (e.g., physician, dietician, exercise physiologist) at their regularly scheduled appointments, while Tess provided an extra layer of care outside of office hours. With the apparent gap between the need for behavioral counseling and the capabilities of weight management programs to deliver this counseling at the intensity and frequency needed, the behavioral coaching chatbot can be another resource to help extend the care delivered by health care providers. Further, the brief and frequent on-demand "conversations" that reiterates messaging initiated in the office setting may have synergistic as well as additive effects, especially with younger populations.

Limitations include gradual program adjustments, limited generalizability, and a lack of an experimental design to control for factors (known and unknown) to ensure detection of a treatment effect. As this was the initial feasibility study, system and content enhancements were made to Tess throughout; therefore, clinicians and patients who interacted with Tess later on in the study may have had a different experience than those earlier in the study. For example, the administration user interface was modified to allow the clinician to add reasons why targeted behavior changes were beneficial and Tess's machine learning enabled the emotion and topic recognition and replies in conversations to be improved. The generalizability of the results may be limited in scope given various factors, such as the sample size (n = 23), resource-based factors (e.g., socioeconomic status (SES)), and the chosen population. Tess has been shown as feasible for constant of the shown as feasible for the shown as fea 23 teen patients and greater integration with EHRs may increase future scalability. All patients needed to have access to technology, specifically a text-messaging capable device, although the high rates (about 95%) of cell phone ownership in the USA, even among various SES levels, S illustrate that access to cell phones may not be a significant challenge in the USA [30]. Relevance of results are likely higher for providers of and patients/families seeking weight counseling, possibly reducing generalizability to those with other conditions. However, Tess has the ability to expand beyond this population and intervention focus. Collecting effectiveness data and utilizing outcome measures in future studies could allow better tracking and more clearly demonstrate behavioral change, such as the significant Patient Health Questionnaire-9 (PHQ-9) score reductions observed in the Woebot study [24]. Conducting

future research with a larger sample may also enable more statistical power and insight into patient outcomes. Further, future research should explore the clinicians' perspective in order to optimize usefulness and gather a more holistic view of the acceptability and usability of Tess integrated in a multidisciplinary setting and approach.

CONCLUSIONS

Overweight, obesity, and prediabetes are prominent health concerns among American youth [1]. There are some challenges with the current fourtier treatment approach for weight management, including a lack of service utilization of the first two tiers, attrition, limited access to necessary resources (i.e., tier 3 care), and other treatment barriers [7]. Given that technology is omnipresent and nearly unavoidable in today's society, particularly among youth, it behooves the field of psychology and medicine to leverage the already established accessibility and attractiveness of tech for treatment benefits. Clinicians are challenged with providing sufficient behavioral counseling for weight management to have a meaningful impact. BITs, like artificial intelligence, may offer more immediate and comprehensive access to support for patients by extending their existing care—a promising future for the field. Engaging individuals through established and commonly utilized communication channels may increase "buy-in," engagement, and helpseeking behaviors, while decreasing stigma. Tess, the behavioral coaching chatbot, has been successfully implemented to help support teens in a weight management program and has the ability to expand further. Future research examining the benefits and challenges with artificial intelligence will aid in the development, production, and dissemination of technological tools that could have a significant

Compliance with Ethical Standards

Funding: While no funding was provided in order to complete this study, services were provided pro bono by both X2AI (staff support, access to Tess) and Nemours Children's Hospital (staff support).

Conflict of Interest: Please note, authors Angela Joerin and Michiel Rauws are employees of X2AI, which created the behavioral coaching chatbot, Tess, and therefore have financial interest in that company.

Authors' Contributions: AJ, MR and LNW contributed to the collaboration between X2AI and Nemours Children's Hospital, the customized version of Tess for this study, and the data collection. TNS analyzed the data and is primary author of the manuscript. All authors reviewed, revised, and approved the final manuscript

Ethical Approval and Informed Consent: All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. For this type of study, formal consent is not required. This article does not contain any studies with animals performed by any of the authors.

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