Study Protocol & Analysis Plan

Title: Engagement and Clinical Impact of the Teleo Virtual Therapy Platform in Clinical Settings

NCT06364137

Last Updated: 09/05/2023

PHS 398 Research Plan

OMB Number: 0925-0001
Expiration Date: 01/31/2026

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Tracking Number: GRANT13970172
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A. Specific Aims

MainSquare Co. (dba "Teleo") is developing a HIPAA-compliant virtual therapy room to transform how clinicians deliver psychotherapy to children remotely, improving client engagement over standard video conferencing platforms (e.g., Zoom). One in 5 children have a mental health disorder.[1] Remote teletherapy can help by enabling more accessible, convenient, and lower-cost care for children.[2] Given these advantages, **mental healthcare providers are permanently adopting telehealth.** As of September 2022, 88% of mental health treatment providers offered Telehealth, versus 39% in April 2019.[3] **Unfortunately, clinicians working with children remotely experience low in-session engagement.**[4] Today, 50-70% of children end treatment early due to low engagement[5] and the median number of sessions attended is one.[6] **Low engagement is tied to worse clinical outcomes in children**[7] and reduced revenue for health systems due to no-shows,[8,9] treatment drop-out,[10,11] and therapist distress / provider turnover.[12-14] In-session engagement – active involvement in an intervention – is associated with improved outcomes for depression,[15,16] anxiety,[17] and substance disorders[18,19]

Teleo improves client engagement by 1) integrating evidence-based therapy tools, worksheets, activities, and games – from Teleo or providers – into a single virtual space with video conferencing, eliminating platform switching and streamlining use of evidence-based practices (EBPs); 2) making interventions more interactive through new two-way mirroring technology, eliminating screen and link sharing, and making previously one-sided activities highly collaborative; and 3) making virtual environments personalizable to each client. **Teleo is in pilot-use by 101 early-adopting clinicians. Of these, 83% say Teleo improves client engagement**; 42% say Teleo improves clinical outcomes; 88% would be disappointed without Teleo. Teleo is in pilot at Seneca – the largest community mental health provider to youth Medicaid populations in CA – and cleared IT/compliance at Montage Health, a large community health system (6,000+ child psych patients / month). Teleo has commercial interest from 40 other organizations, including Kaiser Permanente, Stanford Children's, and Spring Health. This STTR funds otherwise impossible empirical validation called upon by early partners.

Phase I Specific Aims. In Phase I, we conduct a pilot randomized control trial (RCT) to evaluate the potential for Teleo to improve pediatric patient engagement in teletherapy relative to standard video conferencing.

- **Aim 1:** Collect qualitative feedback from N = 12 therapists and N = 12 children using the platform to identify and develop additional features to promote higher engagement (e.g., additional room backgrounds, additions to Teleo's activity library, and increased room personalization).
- **Aim 2:** Conduct a pilot RCT (N = 42, 21 per arm) to evaluate if Teleo improves patient engagement compared to standard video conferencing (e.g., Zoom) using well-established measures – PRIME-O (modified) video coding[20] (session 1 only; conceptual domains (CDs): cognitive, affective, behavioral), MTT-Y/MTT-CG[5,21] (sessions 1, 4; CDs: social, cognitive, affective, behavioral), and attendance (sessions 1-4). Patients (ages 5-14, RCADS > 65) are recruited from clinicians using the Teleo platform.
- **Aim 3:** Identify, assess, and address potential barriers to success in Phase II. We will analyze clinician surveys administered *during* participation and perform standardized observational interviews (N = 10) *after* participation with clinicians to measure improvement areas across the standard dimensions of acceptability – such as affective attitude, burden, perceived effectiveness, and self-efficacy.[22]

Phase II Specific Aims. In Phase II, a full-scale RCT will assess if Teleo improves clinical outcomes.

- **Aim 1:** Perform R&D to improve clinician acceptability, clinical workflows, and client engagement in two primary feature development areas to improve engagement – 1) age- and cultural-adaptiveness (e.g., wider diversity of available personalizations) and 2) AI-enablement (e.g., automated treatment planning, clinical documentation, or post-session updates to caregivers). Observational interviews and quantified survey analyses will inform feature priority, development, and iteration, resulting in clinical deployment.
- **Aim 2:** Conduct an RCT (N = 156, 78 per arm) comparing clinical outcomes of patients (ages 5-14, RCADS > 65) treated in Teleo versus standard video conferencing (e.g., Zoom via Epic Virtual Visits). Randomization will occur at the client-level, with N > 15 clinicians to reduce effects of confounding factors. Treatment performance via patient outcomes will be measured with RCADS before treatment and after sessions 4 and 12 (or end of treatment, if first). Again, MTT and EHR data will be collected plus a subsample of video recordings for coding (N = 20, 10 per arm). N ≈ 50 will be recruited from Stanford (25 per arm) and N ≈ 106 (53 per arm) will be recruited distributively from clinics using Teleo.
- **Aim 3:** Analyze EHR data for Teleo versus control groups 1) *throughout treatment* to measure improved practice performance, e.g., changes in cancellations / no-shows and clinician satisfaction; and 2) *6 months following treatment* to measure value-based care outcomes (i.e., indications of reduced total cost of care), e.g., changes in treatment duration / termination and need for medication.

B. Significance

B.1 Teletherapy with children

Accessible, convenient, and lower-cost pediatric mental health care is a significant unmet medical need. One in 5 children has a mental health disorder,[1] costing the US approximately $247B annually.[23] Mental health accounted for more than 25% of all hospitalization days for children and teens aged 3-17.[24] In 2021, 30% of female students grades 9-12 seriously considered attempting suicide (up from 24.1% in 2019) and 23.6% made a suicide plan.[25] Half of all mental health disorders onset before 14 years old, and 75% of mental health disorders begin before age 24.[26] **Effective early intervention (e.g., before age 14) in mental illness is critical** and may successfully modify psychopathological risk trajectories,[27,28] enabling higher long-term functioning and resilience, with potential lasting effects on success in adulthood.[29] **Unfortunately, accessibility to care for children is poor** – 80% of children with mental, emotional, or behavioral disorders do not receive care from a mental health provider[30] and 77% of US counties have a severe shortage of mental health professionals.[31]

Utilization of telehealth services (delivering patient care via telecommunications technology) increased markedly during the COVID-19 pandemic.[32] In April 2020, overall telehealth utilization for office visits and outpatient care was 78 times higher than in February 2020 and by April 2021, 60% of mental health practitioners currently had full caseloads solely on telehealth.[33] Remote therapy removes barriers to access care by making treatment more convenient and lower-cost for children (e.g., transportation not required to reach providers). For providers, remote care is more financially viable – 1) no-shows and cancellations decrease from telehealth in both safety-net populations[34] and academic practices (e.g., due to higher convenience),[35] 2) services become scalable beyond real-estate and geographical constraints, 3) services become resilient to disaster events (e.g., pandemics, extreme weather, snow), and 4) mental health providers may be more productive[36] and satisfied[37] using telehealth. Given these advantages, **mental healthcare providers permanently adopted hybrid care models with a significant telemedicine component.** As of January 2022, 46% of mental health appointments were Telehealth[38] (versus 8% of all outpatient visits)[3] and today, rates may be higher. As of September 2022, **88% of mental health treatment facilities offer telehealth services**, compared with 39.4% in 2019.[39] In February 2023, Teleo interviewed child mental health teams at Kaiser Permanente Northern California and Mass General Brigham – which were utilizing telehealth for 60% and 70% of appointments, respectively (see fig. 1).

Telehealth is here to stay; five tailwinds solidify the shift to hybrid care models: 1) practices offering flexible work arrangements to retain scarce providers amidst high demand for care, 2) shrinking health system margins incentivizing reduction of care costs, 3) remote treatment demonstrating effect parity,[40] 4) payment parity from private insurers and Medicaid for telehealth services,[39] 5) interstate licensure agreements,[39] 6) a "new generation" of providers trained on digital tools, and 7) workflow- and capability-improving technologies.

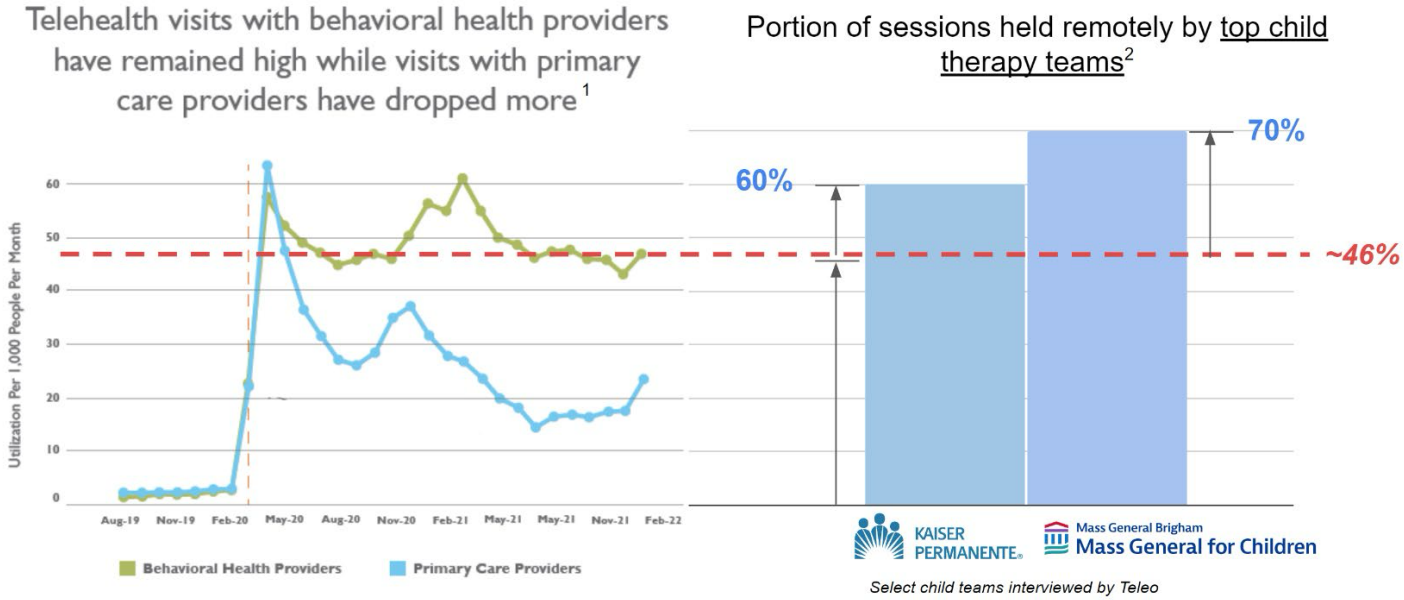


Fig. 1. ~46% of mental health visits are remote (all ages); this number is 14-24% higher at major child clinics[38] (Teleo observational interviews, N = 2).

B.2 Current telehealth platforms for pediatric mental health care are suboptimal

Sudden telehealth adoption led to use of sub-optimal platforms for children's therapy

Telehealth was not considered an effective medium for children until forced by the pandemic, during which providers adopted and adapted existing video conferencing solutions – Zoom, Doxy.me, Microsoft Teams, etc.

– as “standard of care”, regardless of their suitability for kids. These platform’s video and adjacent features (e.g., screen sharing) were originally designed to facilitate corporate meetings rather than one on one care delivery to children. This medium directly contrasted the in-person environment, which was highly contained, required little technical literacy, provided greater intimacy, enabled easier use of EBPs – many of which are physical or activity-based (e.g., CBT worksheets, art activities, play therapy, toys) –, and even allowed children to direct sessions or choose from a selection of interventions tailored to their clinical presentation. **Today, there is no virtual platform designed to implement activity-based interventions for children in a telehealth environment.**

Standard video conferencing tools exacerbate patient access and engagement challenges

Clinicians working with children remotely experience low in-session engagement. Observational studies show the “saliency, engagement, and collaboration” of on-screen communications platforms make it “more difficult to engage a child client in psychotherapy via [telehealth].”[5] Platform improvements are needed to improve deficits relative to in-person, including “attention and fatigue” and **poor “client interest”, “provider comfort” and “session focus”.** One clinician summarized, “telehealth is great with adults, good with teens, and a struggle with kids.”[5] These challenges have exacerbated 1) poor accessibility as clinicians treat older clients to retain benefits of telehealth while avoiding challenges specific to treating kids on Zoom, causing a 19% decrease in availability of telehealth for children[5]; and 2) poor attendance, whereby **25% of telemental health cancellations and no-shows with children are due to low patient engagement**.[8] **Given engagement preempts treatment success[21], and the broad adoption of telehealth, a solution to low engagement is urgent and critical.**

Today, **50-70% of children end treatment early due to low engagement[21] and the median number of sessions attended is one**.[6] As a result, top child engagement researchers claimed in 2023 that, “Low engagement is the most ubiquitous challenge among youths and families with mental health needs”.[41] Low in-session engagement is typically associated with younger clients walking away or losing focus, or older clients being distracted with other applications – which over 50% of therapist reported as a primary challenge (Teleo observational interviews n = 21). **Low engagement is a contributing cause of worse clinical outcomes in children** (e.g., due to weaker therapeutic alliance[7]) and reduced revenue for health systems due to no-shows,[8,9] treatment drop-out,[10,11] and therapist distress / provider turnover.[12-14] In-session engagement – active patient involvement in an intervention – is associated with improved outcomes in evidence-based interventions for depression,[15,16] anxiety,[17] and substance use disorders.[18,19] **While there are over 1000 good EBPs available to clinicians to treat children, an engaging delivery pathway in the digital environment is needed to make them accessible via telehealth.[42]** Should Teleo improve children’s engagement, the standard of remote mental health care could easily be upgraded, leading to important improvements in child mental health care.

Alignment with NIMH’s strategic plan

In addition, over the last half century, the NIMH has successfully focused on developing interventions for *treatment* (~1300+ RCTs) but less so interventions for *engagement* (~55 RCTs).[5,21] Among 52 engagement RCTs since 1976, 112 engagement measures were used: 61.6% of measures reflected treatment attendance, with far fewer representing other behavioral (e.g., in-session participation or out-of-session homework completion), cognitive (e.g., expectancy or understanding of therapy), or social (e.g., therapeutic relationship) dimensions. Measuring youth (19.2% of studies) or caregiver (26.9%) perspectives of their own engagement was infrequent relative to use of clinic records, in part due to the overreliance on attendance as the primary indicator of engagement.[21] Thus, considering ways to better align measurement with the multidimensional, dynamic, and transactional nature of engagement would significantly advance science and practice.[41] Teleo’s access to video, audio, and activity feeds from the session, combined with advances in AI, may uniquely enable automation of video coding for real time or post-processed engagement measurement – which could provide the multi-dimensional approach called upon by the literature. Preliminary R&D with AI in Teleo conducted in Phase II, Aim 2 could contribute learnings towards development of novel approaches.

Research topic areas of emphasis for the NIMH’s Division of Translational Research for this FY24 SBIR/STTR omnibus solicitation cycle include: 1) "Web-based tools and biosensors to enhance prevention, early identification and treatment of pediatric mental disorders by various educational and health professionals” and 2) “Mental health services research to improve the access, continuity, equity, value, quality and outcomes of mental health care, as well as to improve the dissemination of information about and the implementation of effective interventions, to strengthen the public health impact of NIMH research.” Towards both ends, Teleo is a web-based tool that aims to empower mental health professionals to facilitate more engaging and effective care with respect to current standards of virtual care, and more accessible and equitable care with respect to in-person care. Towards equity and access specifically, Teleo enables high care standards for delivery of therapeutic interventions for individuals affected by high barriers to access, such as an unbalanced geographic concentration of providers, health and mobility challenges, and low social determinants of health.

B.3 Teleo solution

Teleo is developing a HIPAA-compliant virtual therapy room for children that transforms how clinicians deliver therapy to children remotely, improving client engagement versus using standard video conferencing platforms (e.g., Zoom). There are 4 main components to the Teleo platform (see fig. 2): 1) Virtual therapy room – an engaging, personalizable, interactive space where both clients and therapist can see each other's activity in the room and collaborate; 2) Activity bank of over 150 categorized, evidence-based resources, filterable by EBP (e.g., CBT, DBT, mindfulness), appropriate age range (e.g., 5-8, 12-14, 16-17), topic (e.g., emotional regulation) and type (e.g., worksheet, game); 3) Video conferencing, and 4) Therapist controls – to edit the room (e.g., swap interventions using the Activity Bank, add/edit/delete objects in the room), start/end sessions, and remove mouse control to regain client focus.

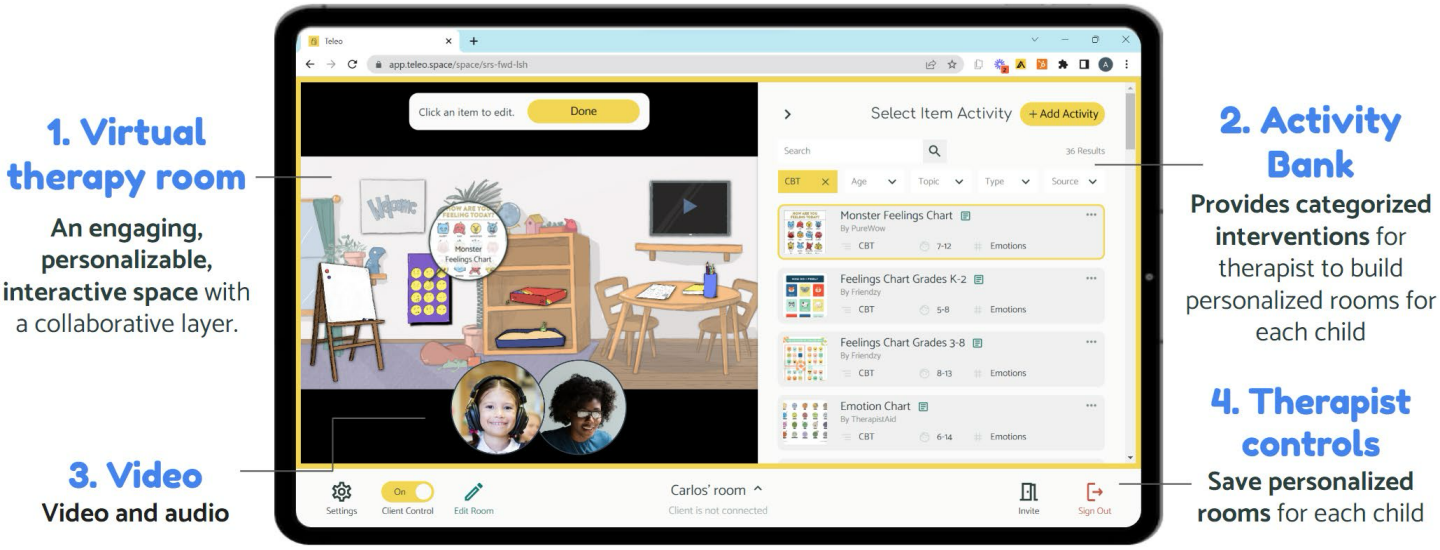
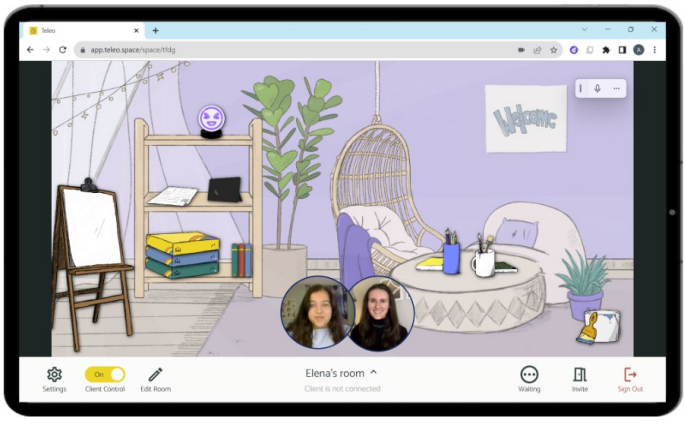


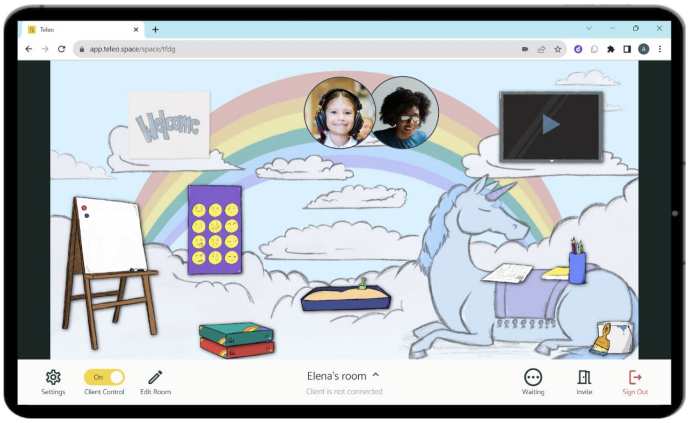
Fig. 2. Four main components of the Teleo care delivery platform (single view)

Fig. 3a-d showcases these 4 components. Fig 3a-b show room personalizations by age and interest; Fig. 3c shows how clinicians can access out-of-the-box resources across ages, approaches, and clinical presentations through the Activity Bank – reducing administrative burden to find, deploy, and refresh interventions before and during sessions. In the future, Teleo will aim to help automate treatment planning, intervention deployment, and clinical documentation using AI, leveraging video, audio, and activity feeds from sessions. Fig. 3d shows "Talk mode", which enables seamless switching between activity- and talk-based interventions.

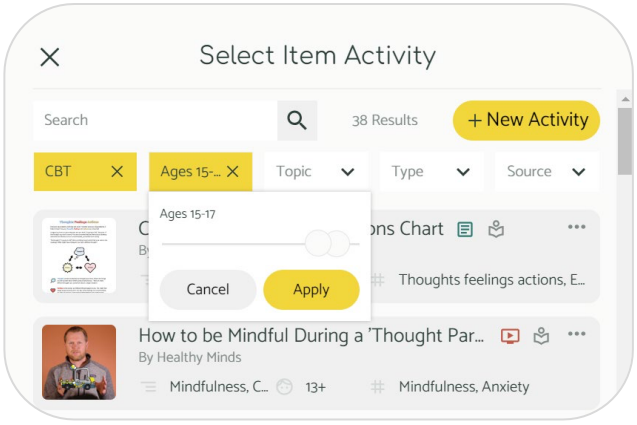
Child engagement is viewed as a multi-dimensional construct across *social* (e.g., therapeutic alliance), *cognitive* (e.g., expectancies related to treatment effectiveness, understanding of treatment approach), *affective* (e.g., emotions related to treatment such as hopefulness or frustration), and *behavioral* (e.g., attendance, active participation in session, homework completion) dimensions.[43-45] Becker and Chorpita (2016) propose a multidimensional measurement framework with five domains of treatment engagement organized around the acronym REACH: *relationship* (e.g., therapeutic alliance); *expectancy* (e.g., beliefs and/or expectations about how helpful treatment will be); *attendance* (e.g., barriers to attending or being on time for treatment sessions); *clarity* (e.g., shared understanding of treatment goals and approach); and *homework* (e.g., active participation and completion of work assigned as part of therapy by youth and family, both in and between sessions).



a. Virtual room – example older room configuration



b. Virtual room – example younger room configuration



c. Activity Bank – filters include age and approach



d. Video – larger mode enables talk therapy

Fig. 3a-d. Four main components of the Teleo care delivery platform (individual views)

Teleo aims to improve engagement across all REACH dimensions through three primary innovations: First, Teleo integrates age-tailorable, evidence-based therapy tools, worksheets, activities, and games – provided by Teleo or providers – into a single virtual space with video conferencing, eliminating platform switching and streamlining use of EBPs (Clarity, Homework); Second, Teleo makes these interventions more interactive through new two-way mirroring technology, eliminating screen and link sharing, and making previously one-sided activities highly collaborative (Relationship, Expectancy, Attendance, Homework). Third, Teleo rooms can be personalized for each client (e.g., based on clinical presentation, age, and interests), saved, and retrieved before sessions, improving continuity, familiarity, and rapport across sessions (Relationship, Expectancy, Homework).

B.4 Commercialization Potential

Teleo helps providers improve engagement, and possibly clinical outcomes, for patients and commercial outcomes for practices. To enable rapid adoption of Teleo, STTR research is required to gather clinical validation points as we simultaneously develop return-on-investment (ROI) case studies in commercial pilots. By improving patient engagement, research suggests Teleo may not only improve clinical outcomes,[15-19] but also practice revenue by preventing no-shows,[8,9] treatment drop-out,[10,11] and provider turnover.[12-14] In addition, Teleo increases clinician productivity by streamlining and enhancing preexisting treatment workflows for clinicians and patients through telehealth. Since Teleo improves poor telehealth workflows in use today, it does not require FDA approval as an independent intervention, and thus has begun commercializing:

- Teleo is used by 101 clinicians in 40+ health systems, agencies, and clinics in 26 states and Canada.
- 6 small practices pay Teleo between $15-59 / clinician / month.
- 440+ children and teens have been treated for 370+ session hours in Teleo
- **83% of clinicians believe Teleo improves engagement**; 42% believe it speeds up clinical outcomes; 88% of clinicians would be disappointed were Teleo taken away (Teleo internal survey, n = 16).
- Teleo has a 73 Net Promoter Score (NPS) (99th percentile); 79% of users would promote Teleo to colleagues and 76% of Teleo users are referred by other clinicians (Teleo internal survey, n = 16).
- In a pilot with Seneca, Teleo has **increased clinician revenue by 27%** ($5,323 per month per clinician), 80% of which was **direct revenue uplift from improved client engagement** (reduced cancels and extended session times); 20% was operational productivity gains (preventing driving, saved prep time).
- Teleo is launching a pilot on 10/2/23 with Ohana at Montage Health (large CA health system), after clearing a 4-month IT/compliance process. Montage intends to sign a non-binding letter of intent to pay $200-400 / clinician / month for continued use after the pilot, assuming we hit our expected pilot metrics.
- Teleo's commercial traction enabled it to raise ~$1M from 22 top investors, including Sequoia Capital.

C. Innovation

C.1 Teleo

Teleo replaces corporate teleconferencing platforms (e.g. Zoom) as the remote clinical standard of care for treating children with mental health challenges. While chat and screen share are useful features, Zoom has no features specifically designed for healthcare applications, let alone pediatric behavioral health. **With Teleo, therapists can use evidence-based interventions to build and save personalized, interactive rooms for each client.** Room backgrounds, the arrangement of items, and other elements (e.g., posters on the wall) can all be personalized. In addition to enabling providers to load any interventions (websites, files, etc.), Teleo provides over 150 mental health resources (e.g., worksheets, art activities, games, and books), that are categorized by evidence-based approach (e.g., CBT), appropriate age range (e.g., 5-8, 12-14, 16-17), topic (e.g.,

mindfulness, cognitive distortions), and more. Today, Teleo enables therapists to deliver interventions and resources in an engaging platform that kids love and connect with. In the future, Teleo may be accessible to patients and caregivers between sessions, further improving continuity and homework engagement.

C.2 Preliminary Data

C.2.1 Overview

To ensure success in Phase I and Phase II aims, we collected 4 areas of preliminary data over 18 months: 1) clinician research, 2) platform usage, 3) engagement and outcomes and 4) implementation considerations.

C.2.2 Clinician user research

Platform usage by remote child therapists and challenges faced

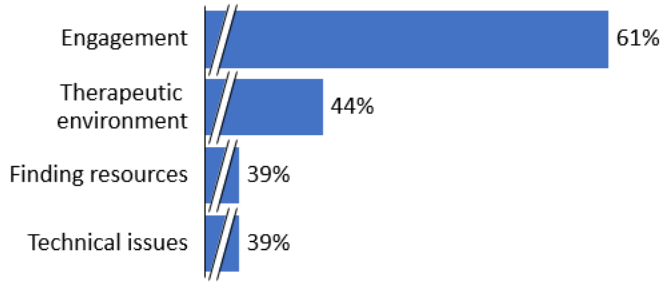


Fig. 4. Top challenge areas (% participants mentioning)

Teleo surveyed N = 63 clinicians in a Facebook forum to breakdown telehealth platform use: Zoom (35%), Doxy.me (31%), Google Meet (11%), Simple Practice (9%), and other (15%); ~10% of therapists use >1 platform to handle poor internet connections or work with multiple agencies.

Focus is a challenge on these platforms. Of therapists interviewed in one internal study (N = 21), **over 50% reported child clients leave the screen within 15 minutes of 45-minute sessions.** In another observational interview study, remote child therapists (N = 18) who went from in-person prior to remote during the pandemic were asked "What are your three greatest challenges working with kids remotely?". Responses were recorded and grouped. 4 challenge areas had n > 6 responses (see fig. 4), all of which Teleo aims to address: low engagement (61%), diminished therapeutic environment (44%), difficulty finding resources (39%), and technical issues (39%). Pain-points within these areas are in Table 1.

Group 1: Platforms are inherently low-engagement (61%) • Very difficult to facilitate interactive or collaborative activities • Hard to play games, do art, interact through activities • No undirected space for kids to explore • Can't collaborate well (without giving screen control) • Must be creative because environment itself not engaging	**Group 2: Diminished therapeutic environment (44%)** • Confidentiality • Distractions • Lack of separation of therapy space • Maintaining professional/therapeutic boundaries • Ambiance / comfort in the space
Group 3: Difficulty finding resources (39%) • Finding available tools • Preparing for sessions • Staying within laws / regulations / literature	**Group 4: Technical issues (39%)** • Internet connection • Computer lags / crashes from opening too many browser tabs • Restarting computer frequently

Table 1. Pain-points mentioned within top 4 challenge groups

To mitigate these challenges when working with kids remotely, therapists developed many solutions, including:

- Using collaborative whiteboard features in video platforms (e.g., Zoom whiteboard)
- Downloadable worksheet libraries (e.g., Therapist Aid, PsychPoint)
- Virtual therapy rooms in Google Slides (e.g., available on Teachers Pay Teachers)
- Replacing physical resources (which require postal) with websites (e.g., Karen Fried puppet house)

These solutions are low-fidelity, disparate to find, and labor intensive to facilitate during sessions.

Pre-pilot deployment survey to early-adopting users (N = 25)

Teleo surveyed its first 25 clinicians prior to onboarding. Here are major observations:

- 38% disagree their remote sessions are engaging – which likely underestimates, given self-serving bias
- Clinicians most intended to use the platform with 11-15 year olds, followed by 6-10 year olds
- Clinicians intended to employ the following approaches, in order of frequency: CBT, play therapy, and trauma-focused, attachment-based, art, mindfulness

C.2.3 Usage data

As of 8/31/23, Teleo has been used by 101 therapists with 448 clients for 971 sessions. After one month on the platform, users (N = 16) were surveyed with the following conclusions:

- 88% of clinicians would be "very disappointed" or "disappointed" were Teleo taken away from them.
- Teleo has an NPS of 73 (99th percentile for healthcare); 79% of users would promote Teleo to colleagues.
- 76% of Teleo users are referred by other clinicians (Teleo has spent $0 on marketing).

In addition, N = 7 testimonials were captured across licensures and geographies; N = 3 are in Table 2. Therapists repeatedly cite improved client engagement.

State	License	Testimonial
CA	LMFT	*Teleo provides me the tools to **engage kiddos who are typically difficult to engage via teletherapy**. The Teleo playroom has my clients looking forward to teletherapy for the very first time! Children love using Teleo, but younger kids are obsessed. With Teleo, I have can work with these clients for the full session length. I'm seeing a different side of my clients that I've never seen before.*
NY	LCSW	*I am beyond grateful for the creation of this platform. I have been able to enhance the work I do with children in ways that were not otherwise available. They can feel like they truly have their own safe place to explore new tools, process trauma through play, and so much more. I have been able to **make therapy that much more accessible to children and their families**.*
GA	LCSW	*Teleo is an **innovative way to make engaging with clients easy and accessible***

Table. 2. Sample testimonials from Teleo users

C.2.4 Engagement and outcomes

Engagement survey data (N = 16)

After 1 month on the platform, users (N = 16) were surveyed with the following conclusions:

- **83% of clinicians say Teleo improves client engagement; without prompt, 64% of clinicians cited improved engagement as Teleo's main benefit**, followed by easier access to therapeutic tools (21%).
- 42% of clinicians agree their client's skills, symptoms, or impairment in functioning improve more quickly when using Teleo than when they use video conferencing alone.

Pre-post Teleo pilot impact study (N = 6)

Teleo conducted a survey asking therapists questions on a 7-point Likert scale, before beginning to use Teleo and 3 months after. **Results showed a statistically significant increase in engagement with an effect size of 1.2 ($p < .05$)** whereby responses to "My teletherapy sessions are engaging" moved from an average of 5.6 (Between "Somewhat agree" and "Agree") to 6.1 (Between "Agree and "Strongly agree"). While only engagement showed statistical significance, reduction in clinician burnout showed promise were we to increase sample size ("I feel burnt out or exhausted in my job": avg. change = -0.83, $p < .15$).

Preliminary video coding data (N = 7)

Phase I and II use video coding to better understand the underlying, input mechanisms of action that Teleo effects in-session. Understanding these in-session mechanisms will enable us to make more precise product improvements in Aim 1 of Phase II that increase output engagement metrics, like attendance and MTT scores. We expect these improvements also affect clinical outcomes, which we will study Phase II, Aim 2.

In preparation for Phase I, Teleo conducted a preliminary video coding study with N = 7 clients, recruited by clinicians on the platform. The primary objective was to de-risk Phase I by developing and implementing a modified validated video coding instrument, testing remote screen recording procedures, and demonstrating client recruitment from existing clinician users on Teleo. A secondary objective was to substantiate if Teleo improves client engagement. An IRB-approved protocol was designed to evaluate client engagement on Teleo versus standard video conferencing. Clinician consent, caregiver consent, and client assent were acquired.

Clinicians delivered two sessions to each client in the study (crossover): one session through standard video conferencing (control) – e.g., Doxy.me, SimplePractice telehealth – and one session through Teleo (treatment), typically 1-2 weeks later. To randomize against recency effects on post-study questionnaires, the order of platforms used was not controlled. Clinicians were verified as equally proficient with both platform types. Clinicians used a HIPAA-compliant screen recorder to record sessions on both platforms. Recordings captured both video and audio of the client and clinician, as well as other on-screen activities such as those completed in Teleo or using features in control group platforms, like screen sharing or whiteboards. Videos were coded by a Clinical Assistant Professor, PhD in Child Psychology at Stanford without intercoder reliability; training was administered to the coder. The code was an adapted version of the Pediatric Rehabilitation Intervention Measure of Engagement-Observation (PRIME-O). PRIME-O is an observational measure of indicators of 3 dimensions of engagement – affective, cognitive, and behavioral (overlapping theoretical underpinnings to REACH)[5] – enabling accurate identification of signs of engagement for client, clinician, and joint dimensions.[20] In addition, clients completed questionnaires modeled on the MTT, containing one adapted question per REACH domain.

Teleo successfully recruited N = 7 clients from 2 clinicians using the Teleo platform (clinician 1: 4 clients; clinician 2: 3 clients), generating n = 14 session videos (control: n = 7, Teleo: n = 7). PRIME-O coding results are in Table 3. **Teleo demonstrated a 41% improvement in engagement score over standard video**

systems with an effect size of 1.4 (p = 0.047). Teleo showed a positive effect (p < 0.05) in 4 of 10 PRIME-O dimensions: use of language, 1.4 (clinician); overall comfort and confidence in engaging the client, 2.4 (clinician); listening/communication behaviors, 1.2 (clinician); collaborative nature of the interaction, 1.4 (client and clinician). Three additional dimensions were trending towards significance and warrant further examination at higher sample size (0.05 < p < 0.12): interest and enthusiasm, 1.2 (client); use of language, 1.0 (client); and openness to what is being said or done, 0.9 (client).

	PRIME-O coding dimension										
	Client				Clinician				Client + clinician		Total
Measurement	1	2	3	4	5	6	7	8	9	10	score
Control group (n = 7), avg. score	1.9	1.7	2.1	3.1	3.0	1.4	1.3	1.7	3.1	1.0	20.4
Teleo group (n = 7), avg. score	3.0	2.7	2.9	3.1	3.3	2.6	3.0	2.6	3.3	2.3	28.7
Average change	**62%**	**58%**	**33%**	0%	10%	**80%**	**133%**	**50%**	5%	**129%**	**41%**
p-value	**0.052**	**0.078**	**0.110**	0.500	0.229	**0.015**	**0.008**	**0.023**	0.409	**0.024**	**0.047**
Cohen's effect size	**1.2**	**1.0**	**0.9**	0.0	0.4	**1.4**	**2.4**	**1.2**	0.1	**1.8**	**1.4**

Table 3. Summary of video coding comparing engagement scores in Teleo and Zoom

Client survey results are shown in Table 4. **Across REACH domains, 43% of client responses preferred Teleo whereas 11% preferred the control platform** (46% showed no preference). On the attendance domain, which most directly impacts practice revenue, **58% of clients said Teleo makes them more excited to attend their next session than the control; 0% said the control makes them more excited**. Separately, the survey tested client preference: **No clients preferred the control over Teleo; 4 (57%) clients preferred Teleo over the control** (two preferred it "more" and two "much more"); 3 (43%) had no preference.

Dimension	Question	Control much more	Control more	Equally	Teleo more	Teleo much more
MTT - Relationship	Which platform helped you to get along with your therapist best?	1 (14%)	0 (%)	4 (57%)	2 (29%)	0 (%)
MTT - Expectancy	Which platform will best help you meet your goals in therapy?	0 (%)	0 (%)	4 (57%)	2 (29%)	1 (14%)
MTT - Attendence	Which platform makes you more excited to attend your next session?	0 (%)	0 (%)	3 (43%)	3 (43%)	1 (14%)
MTT - Clarity	Which platform best helped you to understand what you are working on in therapy?	0 (%)	2 (29%)	2 (29%)	2 (29%)	1 (14%)
MTT - Homework	Which platform made it easier to practice new skills?	0 (%)	1 (14%)	3 (43%)	2 (29%)	1 (14%)
Totals		1 (3%)	3 (9%)	16 (46%)	11 (31%)	4 (11%)

Table 4. Summary of survey responses for control versus Teleo across MTT engagement subscores

C.2.4 Study implementation de-risking

Teleo has significantly de-risked various implementation barriers to Phase I and II:

1. *Patient recruitment from Teleo platform:* Teleo intends to distributively recruit from existing users on Teleo for Phase I. Teleo has demonstrated feasibility of approach through a preliminary video coding study.
2. *IT/security compliance:* Teleo has passed IT reviews and security questionnaires in both community-based health settings (Seneca Family of Agencies) and large medical centers (Montage Health).
3. *Acceptability and attrition:* Teleo has high retention and satisfaction among clinicians, which should indicate future acceptability and low attrition rates among clinicians in the study.
4. *Development of novel remote child engagement video coding measurement:* Teleo and its research collaborators have already developed the modified PRIME-O coding measure and tested it in the field.

D. Approach

In Phase I, we will conduct a pilot RCT to evaluate if Teleo improves child engagement in teletherapy compared to standard video conferencing. In Phase II, we will conduct a full-scale RCT to assess if Teleo improves clinical and practice outcomes. The resulting data will help Teleo substantiate its platform in the literature and gain trust and credibility in the market. In addition, in both Phases, Teleo will perform R&D to improve patient engagement and clinical workflows, as mechanisms to improve clinical outcomes and clinician acceptability, respectively. Together, the clinical validation and feature development in Phase I and II will move Teleo towards becoming standard of care for delivering children's behavioral health treatment remotely.

D.1 Phase I Overview

Phase I is about improving patient engagement in remote therapy, given current care standards using video conferencing suffer from poor "saliency, engagement, and collaboration".[4]

D.1.1 Phase I, Aim 1: Conduct R&D to build additional features to promote higher engagement (3 months)

Teleo will conduct focus groups with N = 12 therapists (4 therapists per group) and observational interviews with N = 12 children using the platform (1 month). Each subject will complete surveys to inform product development. Table 5 contains sample survey questions. Teleo will then prioritize, develop, and deploy 3-4 features (e.g., more room backgrounds, expanded activity bank, etc.) (2 months). The output of Aim 1 is feature deployment.

Topic	Question
Current features, in-session	Which of these do you like most about Teleo? (choose as many as you like)
Future features, in-session	Which of these would you most like to have in Teleo? (choose as many as you like)
Future features, out-of-session	Which of these would you be excited to access in Teleo outside of sessions?

Table 5. Sample questions to clients

D.1.2 Phase I, Aim 2: Conduct a pilot RCT to evaluate if Teleo's improves patient engagement (8 months)

With improved engagement features developed in Phase I, Stanford will conduct a pilot RCT (N = 42) to evaluate Teleo's ability to improve patient engagement over standard video conferencing. Engagement will be assessed using well-established measures – PRIME-O (modified) video coding[20] (session 1, reduced n = 10 per arm) and MTT-Y/MTT-CG[43-45] (sessions 1 and 4), and attendance data (sessions 1-4). Clinicians in the study will deliver therapy to clients for 4 sessions, providing opportunity to measure temporal sustainment of any engagement differences). If a client is already getting treatment or ends treatment early, the maximum sessions available will be included. Half of recruited patients will use standard video conferencing (control arm, n = 21) and the other half Teleo (treatment arm, n = 21). Randomization will occur at the client level. N > 8 clinicians recruiting 2-3 patients each will reduce potential impact of confounding factors (e.g., clinician effects).

Patients will be recruited from clinicians already using Teleo. Teleo currently has 87 clinicians active on the platform and expects over 300 by April 2024 (i.e., potential funding award date). The eligible patient population for Phase I and II are identical to preserve applicability of learnings in Phase I to Phase II. Children must be ages 5-14 experiencing anxiety or depression (RCADS > 65). Teleo validated its ability to recruit patients from the platform in a preliminary study. Clients and clinicians will be compensated $100 each for participating. Since Zoom preempted Teleo as a method of care delivery, Teleo clinicians have experience delivering remote therapy to children in both modalities. This limits training required during clinician onboarding.

Clinicians will use a HIPAA-compliant screen recorder (e.g., Droplr) to record all therapy activities. Recordings will capture both video and audio of the client and clinician, as well as other on-screen activities (e.g., therapy activities) completed in Teleo or on the control platform (e.g., screen sharing or use of built-in whiteboards). Video recordings will be coded by two researchers for intercoder reliability using a modified video code with validated psychometrics (see video code section below). In addition, clinicians, patients, and caregivers will complete self-report questionnaires to measure engagement across REACH dimensions.[5]

Sample sizes were determined by power calculation. For coding and survey data, we expect effect sizes of 1.3 and 1.2, based on our preliminary pre-post survey and video coding results, respectively. Although first principles and preliminary data suggest video coding is higher potency, we conservatively assume an effect size of 0.9 for both measures, a sample size of N = 42 (N = 21 treatment, N = 21 control) is required to achieve a power of β = .80 with a significance level of α =.05 (two-tailed). The analysis plan outputs for Aim 2 are two-tailed t-tests at each measurement point for 1) MTT-Y and MTT-CG scores (overall and dimensional subscales), 2) video coding (overall and dimensional subscales), and 3) attendance (proportion of 4 sessions no-showed or canceled). Key findings and data will be published in peer-reviewed journals.

Measuring engagement: Video coding measurement and self-reported MTT

Unfortunately, there is no established video coding rubric to measure child engagement in psychotherapy, let alone in the remote environment; however, for self-reporting on engagement, My Thoughts about Therapy instrument (MTT) is a 35-question survey with 5 subscales and 7 items per subscale aligned with the REACH framework, which is specific to child engagement in mental health treatment. Adjacently, King G., et. al (2019) developed the PRIME-O, an observational measure of 3 engagement dimensions – affective, cognitive, and behavioral – of clients and clinicians in child therapy broadly (e.g., physical, occupational, and speech therapy), enabling accurate identification of signs of engagement and disengagement. While the PRIME-O is not tailored to mental health treatment for children, it provides a video code with good psychometrics with strong overlap with REACH; both cite drawing on affective, cognitive, and behavioral elements required for child therapy engagement.[5] Thus, to retain strong theoretical underpinnings and a validated code, we modified the PRIME-O

by creating behavioral scoring anchors that reflect our specific remote, mental health context while maintaining the 10 scoring dimensions and three groupings (client, therapist, and client-therapist) of the original PRIME-O. This has the added benefit of strengthening weak scoring guidance in the original PRIME-O. By example, dimension #10 of our modified code is given in Table 6.

C. Client-Therapist Interaction Items (dealing with reciprocity; mutual engagement)	
10. Collaborative nature of the interaction *Overall sense of mutual contribution to the interaction and collaboration*	0. *Not at all*: There is no sense of mutual contribution to the therapy. One party dominates the discussion and activities, while the other is a passive recipient. There is a complete absence of reciprocal interaction – verbal or non-verbal feedback is rarely sought or provided openly. 1. *Minimal*: There is limited sense of mutual contribution to the therapy. One party tends to dominate the discussion and activities more often. There is a noticeable lack of reciprocal interaction and feedback in the therapy sessions –verbal or non-verbal feedback is seldom sought or provided openly. 2. *Moderate*: There is a moderate sense of mutual contribution to the therapy. Both parties contribute to the discussion and activities. The presence of reciprocal interaction and feedback varies throughout the therapy sessions. There are moments of both seeking and providing feedback, but it is not consistently maintained. 3. *Considerable*: There is a strong sense of mutual contribution to the therapy. Both parties actively contribute to the discussion and activities. Reciprocal interaction is present to some extent, with opportunities for seeking and providing feedback. While there are instances of verbal or non-verbal feedback, there is room for further encouragement and open sharing of perspectives. 4. *To a great extent*: There is an excellent sense of mutual contribution to the therapy. Both parties actively and equally contribute to the discussion and activities. There is a strong presence of reciprocal interaction, both verbally and non-verbally. Feedback is actively sought and openly provided in the therapeutic process.

Table 6. Item 10 of the modified PRIME-O.

For self-reported measures, MTT provides youth (MTT-Y) and caregiver (MTT-CG) versions for key perspectives on child treatment engagement. MTT was informed by a systematic literature review of 112 engagement outcomes[5,21] and frequently used engagement measures including the Working Alliance Inventory,[46] Parent Motivation Inventory,[47] and Treatment Beliefs Questionnaire.[48]

D.1.3 Phase I, Aim 3: Identify, assess, and address potential barriers to success in Phase II (1 month)

Identify, assess, and address potential barriers to success in Phase II. Stanford will analyze clinician surveys administered *during* participation and perform standardized observational interviews (N = 10) *after* participation with clinicians to measure improvement areas across standard dimensions of acceptability for healthcare interventions – such as affective attitude, burden, perceived effectiveness, and self-efficacy.[22] In addition, we will finalize arrangements and collaborate with administrators and clinical leaders at Stanford and distributive cites to finalize implementation steps for Phase II (e.g., IT / security), such as EHR integration (e.g., Epic). The output of Aim 3 is full implementation readiness for Phase II via coordination with IT teams and identification of platform and protocol acceptability improvements via cluster analysis of interview data, similar to that in C.2.2.

D.2 Phase II Overview

The primary goals of Phase II are to 1) improve (Aim 1) and measure (Aim 2) engagement improvements through R&D, and 2) measure the platform's effect on clinical outcomes through an RCT (Aim 2). As secondary goals, Phase II will measure practice performance in Zoom versus Teleo (Aim 3), which will enable comparison to engagement outcomes, and contribute additional data on telehealth clinical outcomes to the literature (though parity is accepted,[40] our understanding of these differences is likely still nascent). A tertiary goal of Phase II is to assess value-based care improvements resulting from any improved engagement or clinical outcomes (Aim 3).

D.2.1 Phase II, Aim 1: Perform R&D to develop new product features to improve clinician acceptability, clinical workflows, and client engagement, leveraging learnings from Phase I (6 months)

Here we perform R&D to develop new product features to improve clinician acceptability, clinical workflows, client engagement, focusing on 1) age- and cultural- adaptiveness and/or 2) opportunities to leverage AI. The former is critical to ensure Teleo promotes equity and access across broad patient populations by design, adding variable aesthetic environments and interactive components as customization options and adding language- and ethnicity-adapted EBPs as pre-loaded interventions. The latter is a new opportunity to reduce clinical burden for existing administrative workflows (e.g., clinical documentation, treatment planning, and session preparation) and automate new, previously negative-ROI workflows that could now *improve* practice performance through increased engagement (e.g., automating intervention suggestions / deployment, clinical documentation, and progress updates to an out-of-session app for caregivers). Potential AI model input-outputs are shown in fig. 5.

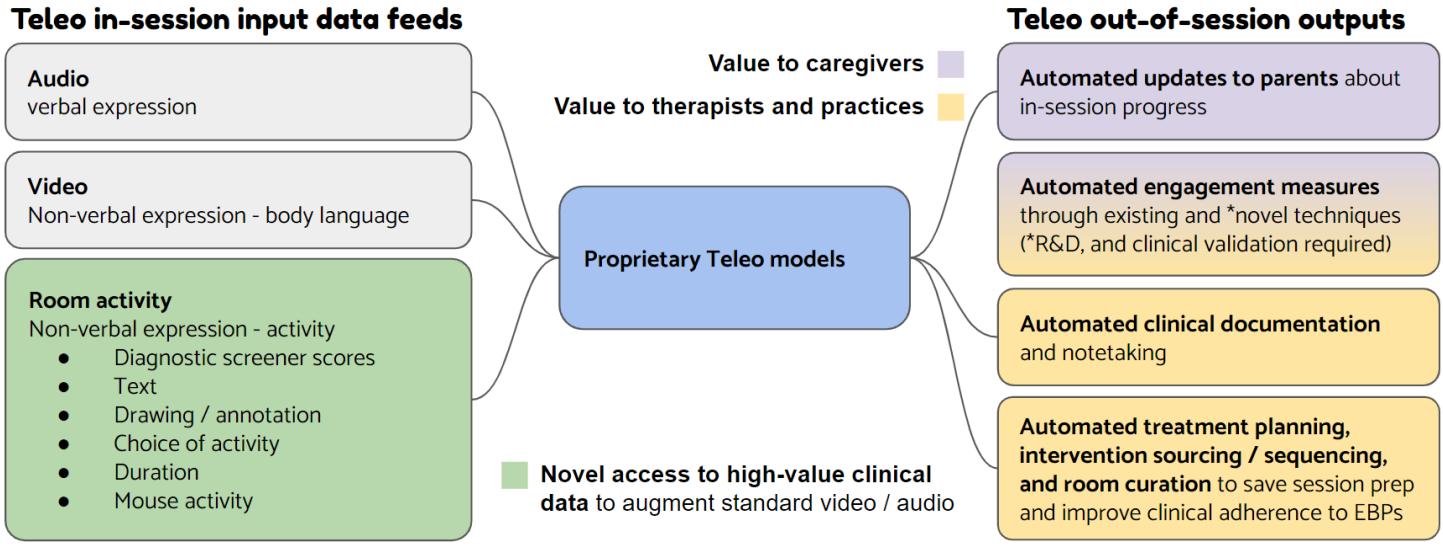


Fig. 5. High-level model diagram to use unique in-session data to automate existing and new clinical workflows with the aim to improve engagement outcomes (to be studied in Aim 2).

Teleo will start Aim 1 by conducting observational interviews of clients to ideate and assess new age-/culturally adaptive features (N = 6) and AI-powered features (N = 6), followed by surveys to each group to quantify desirability and feasibility. Interviews and surveys will take 2 months to design, complete, and analyze – resulting in a feature list with impact rankings and design descriptions. Researchers will then prioritize and build 1-2 features that maximize overall impact with available product development bandwidth. Timing: Feature design and prototyping (1 month); full feature build (2 months); testing (1 month). Output: feature deployment.

D.2.2 Phase II, Aim 2: Full RCT of Teleo's impact on engagement, clinical, and practice outcomes (15 months)

In Aim 2, we conduct an RCT (N = 156, 78 per arm) to measure engagement and clinical outcomes (patients ages 5-14, RCADS > 65) in Teleo versus standard video conferencing with identical EHR-integrated workflows. Engagement measures will be purposefully identical to Phase I to enable comparison of effect sizes after further feature development and deployment in new clinical settings – PRIME-O (modified) video coding[20] (first session only, reduced n = 10 per arm), MTT-Y/MTT-CG[5,43-45] (sessions 1, 6, and 12), and attendance data (all sessions, automated via EHR). In addition, treatment performance via patient outcomes will be measured with RCADS before treatment and after sessions 4 and 12. Clinicians in the study will deliver therapy to clients for 12 sessions, which is generally accepted as a minimum standard CBT module length.[49] If the client is already getting treatment or ends treatment early, the maximum sessions available will be included. Half of recruited clients will use standard video conferencing (control arm, n = 78) – likely Zoom (Stanford) and Microsoft Teams (Ohana) – and the other half Teleo (treatment arm, n = 78). Randomization will occur at the client level. There will be N > 15 clinicians per arm each with at least 10 clients to feasibly minimize confounding factors and multilevel effects (e.g., covariates such as site, study therapist), respectively.[51]

Patients will be recruited from Stanford School of Medicine's Division of Child and Adolescent Psychiatry (n > 50) with additional distributed recruitment from community-based Teleo customers. Anchoring recruitment at Stanford while augmenting via a distributed sites enables multiple benefits: 1) higher patient diversity than that brought by an academic medical center (AMC) that may lean towards affluent, white patient populations while simultaneously 2) representation of AMCs, who may be an important future customer segment Teleo, though possibly not until *after* the publishing of clinical validation, given their research-orientation. 3) Since Teleo is a startup whose composite of future customers cannot be fully known until closer to Phase II, choosing a representative sample of site settings and populations two years from now helps to ensure study data is most relevant to Teleo's future customers. Thus, in summary, enabling a more heterogeneous patient population (e.g., geographies, demographics, and practice types, e.g., academic medical settings versus community-based practices) will enable the trial to mitigate future research-practice implementation gaps through mechanisms other than improved patient engagement.[42] To retain access to these benefits while preemptively removing feasibility risk at the time of grant review, Teleo has acquired letters of support from two community-based health organizations, Ohana Center for Child and Adolescent Behavioral Health (within non-profit health system) and Seneca (non-profit agency), to support patient recruitment, atop Stanford's commitment of N > 50. Stanford is subcontracted while distributed sites will be finalized and selected by end of Phase I Aim 2 and receive $500 per patient enrolled, as budgeted.

Patient selection criteria for Phases I and II are identical to better enable comparison: children ages 5-14 experiencing anxiety or depression (RCADS > 65). The vast pool of RCTs on children's mental health interventions suffers from a severe patient attrition problem[41] which has been recently shown to span digital mental health intervention.[50] Both Phases will address this through incentives upon study completion – a $100 gift card for caregivers for their participation in the study (e.g., caregiver questionnaire) with their child.

Stanford's use of the Epic EHR will enable more centralized and standardized collection of EHR data from patients, including RCADs, attendance, treatment duration, and related patient data (e.g., need for medication). This additional data collection will enable outcomes measurement (RCADs), practice performance measurement (cancellations, no-shows, and treatment drop-out), and value-based care outcomes (e.g., treatment duration required, need for medication). While Teleo is already collaborating with IT teams at Stanford and Ohana to integrate with their Epic instances, data from distributed customer sites will be collected and uniformized into a consistent, similar format across clinicians and contexts – regardless of site selection.

Given our preliminary effect sizes for self-reported and observational engagement measures are 1.2 and 1.4, respectively, we expect an RCADs outcomes effect of 0.45, given the relationship between patient engagement and clinical outcomes and the comparability of known benchmarks.[52,53] Using the t-test power formula and seeking an iterative solution, the sample required to achieve $\beta = .80$ and $\alpha = .05$ (two-tailed), N = 156 patients (n = 78 treatment, n = 78 control). The analysis plan outputs for Aim 2 are two-tailed t-tests at each temporal measurement point for 1) MTT-Y/MTT-CG scores (N = 156, overall and dimensional subscales), 2) video coding (N = 20, overall and dimensional subscales), and 3) attendance (N = 156, proportion of sessions no-showed or canceled), 4) RCADs (N = 156, overall and subscales). Key findings will be published in peer-reviewed journals.

D.2.3 Phase II, Aim 3: Analyze improved practice performance and value-based care outcomes (3 months)

For both treatment and control groups from Aim 2, Aim 3 will analyze EHR data from 1) *during treatment* to measure improved practice performance – including changes in cancels / no-shows and treatment dropout (affecting medical reimbursement) and clinician satisfaction (affecting clinician attrition); and 2) *6 months following treatment* to measure value-based care outcomes (i.e., indications of reduced total cost of care) – including treatment duration / termination and need for medication (both affecting total treatment cost to payers or other risk-bearing entities). Although 6 months post-treatment will be achieved for most patients within the study timeline, we recognize this observational period for the final ~1/4 of RCT subjects in Aim 2 may surpass the grant completion date; Teleo will continue monitoring lagging patients beyond the grant timeline.

Automated EHR database queries of attendance and medication/treatment data will be used to calculate total cost of care for each subject, which will be regression tested versus treatment retention, patient no-show/cancel rates, RCADs, and MTT, enabling determination of significant relationships between engagement (multiple dimension), outcomes, telehealth platform utilized, and cost of care of care. Two-tailed t-tests will be conducted comparing average total cost of care in the Teleo versus the control group. Were Teleo to reduce total cost of care with a statistical significant effect size after randomizing for patient and clinician differences, it would unlock a commercialization pathway through risk-bearing entities, beyond its value proposition to providers – potentially leading to promotion of and compensation for adoption of Teleo across payer-providers networks.

D.3 Timeline

Month	0-3	4-11	12	13-18	19-33	34-36
Proposed Timeline of Phase I Research Plan						
Aim 1: General R&D	■					
Aim 2: Pilot RCT		■				
Aim 3: Barriers to success			■			
Proposed Timeline of Phase II Research Plan						
Aim 1: Potency R&D				■		
Aim 2: Full RCT					■	
Aim 3: Impact analysis						■

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