NYU | DENTISTRY

# Research Subject Informed Consent Form

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| **Title of Study:** | A Stepped Care Approach to Treating Dental Fear: A Sequential Multiple Assignment Randomized Trial for Cognitive Behavioral Treatment via Mobile App and Evidence-Based Collaborative Care<br>Study # s22-01196 |
| **Principal Investigator:** | Dr. Richard E. Heyman, Ph.D.<br>NYU College of Dentistry<br>Cariology and Comprehensive Care<br>137 E. 25th St, 6th Floor, New York, NY 10010<br>212-998-9984 |
| **Emergency Contact:** | Dr. Kelly Daly, Ph.D<br>914-806-5093 |

## 1. About volunteering for this research study

You/your child are being invited to take part in a research study. You/your child's participation is voluntary which means you/your child can choose whether or not you/your child want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you/your child can make you/your child's decision, you/your child will need to know what the study is about, the possible risks and benefits of being in this study, and what you/your child will have to do in this study. You/your child may also decide to discuss this study and this form with you/your child's family, friends, or doctor. If you/your child have any questions about the study or this form, please ask us. If you/your child decide to take part in this study, you/your child must sign this form. We will give you/your child a copy of this form signed by you/your child for you/your child to keep.

## 2. What is the purpose of this study?

The purpose of this study is to compare an intervention for dental fear to the usual approach (i.e., whatever you/your child's dentist typically does to help you/your child manage fear) in reducing patient fear and making dentist appointments more tolerable.

The dental fear intervention has 2 separate steps. Step 1 (the less intensive or ‘light touch’ intervention step) involves using a mobile app that is based on research-backed approaches to handling dental fear on your/your child's smartphone or device. Step 2 (the more intensive treatment step) is reserved for individuals who are still experiencing significant dental fear after completing the mobile app. Step 2 involves a one-hour telehealth session with a mental health provider tailored to you/your child's individualized dental fear.

Because this study compares each step of the dental fear intervention to the standard approach (e.g., whatever you/your child's dentist usually does to help with fear), some participants will be offered Step 1, some Step 1 and Step 2, and 25% of participants will not get either step of the intervention during the study period.

DC 05/08/2020Participants who don't get any intervention will be in the "Treatment Later" condition (TL). TL participants will complete their dental visits as usual and will be offered the opportunity to provide feedback about their experiences with dentists and what they think could improve dentists' training and practice to inform our future work training dental students.

You/your child are being offered participation in this study because you/your child have reported experiencing dental fear.

## 3. How long will I be in the study? How many other people will be in the study?

Up to 1,000 participants are expected to be in this study. The time you/your child spend participating in the study varies. There are two conditions in this study: "Treatment Now" (TN) and "Treatment Later" (TL). The TN study group will receive the dental fear intervention immediately, while the TL study group will be offered the dental fear intervention either later during the study (5 months after you/your child's upcoming dental visit) or after their study participation.

***TN participants***: The intervention portion of participation can last either 1-1.5 hours (for those who only do Step 1) or 2-2.5 hours (for those who do both Steps 1 and 2). Additionally, you/your child will be asked to fill out brief questionnaires after you/your child's upcoming dental visit (which we are calling V1) and a follow-up dental visit (V2) 6 months from now. You/your child will answer the same questions each time, which will take under 10 minutes. You/your child will be asked to fill out these questionnaires 2 times, and you/your child will be actively involved in the study for 6 months (i.e., over 2 dental visits).

***TL participants***: You/your child will participate in a 15-20 minute scheduled interview with a study team member to provide feedback about you/your child's dental experiences. After your/your child's upcoming dental visit which we are calling V1, you/your child will complete the brief questionnaires. These same questionnaires will be repeated 5 months after you/your child's upcoming dental visit V1, after you/your child's next dental visit 6 months later (V2), and after the dental visit 6 months after that (V3). Additionally, some TL participants will be offered one or both of the dental fear intervention steps before the 6-month dental visit. For those of you/your child who are re-randomized to receive dental fear intervention then, you/your child's participation can last an additional 1-1.5 hours for those who only do Step 1) or 2-2.5 hours (for those who do both Steps 1 and 2). The maximum number of times you/your child can be asked to fill out these questionnaires over you/your child's involvement in the study is 4. And the maximum amount of time you/your child can be involved in the study is one year (i.e., over 3 dental visits).

## 4. What will I be asked to do in the study?

If you/your child chooses to take part in this study, we will ask you/your child to sign this consent form first. The entire study is being conducted remotely. At the very start of the study**,** you/your child will be asked to fill out a baseline questionnaire about you/your child's background and demographics, dental history, primary fears and worries about the dentist, oral health, and quality of life. This will take 15-20 minutes. A secure link to the REDCap platform containing this questionnaire will be sent to you/your child.

During the month before you/your child's scheduled dental visit, you/your child will be randomly assigned (like the flip of a coin) to either the ***TN condition*** or the ***TL condition*** after completing the baseline questionnaire. The researcher will not be the person who decides if you/your child will receive the intervention (TN) or provide feedback only (TL). A computer program that uses random numbers will be used to decide you/your child's study condition.

If you/your child is assigned to the ***TN condition*** at the start of the study

- First, you/your child will be asked to complete the mobile app intervention. You/your child will receive instructions for accessing the *Dental Fearless* mobile app, which contains information and research-backed strategies to help you/your child cope with you/your child's dental fear. Completing the mobile app intervention will take between 1 and 1.5 hours depending on how many of the extra segments you/your child do. You/your child can complete the mobile app intervention anytime, anywhere, at you/your child's convenience.

- You/your child will be sent a secure link to answer one question about you/your child's dental fear once you/your child have completed the app intervention. After answering, you/your child may be told you/your child are finished with this phase of the study or you/your child may be offered the individual 1:1 telehealth session. If you/your child is offered the 1:1 session, you/your child will be scheduled to meet a licensed mental health clinician (who is part of the study team) for 1 hour using NYU's HIPAA-compliant version of Zoom. The clinician will help you/your child expand on some of the strategies you/your child learned in the mobile app intervention and personalize the session to you/your child's fears. The 1:1 session will be audio and/or video recorded. Recording is required for participation. You/your child cannot be in this study if you/your child do not want to be recorded.

- After you/your child complete the mobile app intervention, 1:1 telehealth session, or both, you/your child will then go to you/your child's scheduled dental visit. After you/your child's dental visit, you/your child will be sent a secure link to complete a brief (~10 min) follow-up questionnaire about you/your child's dental fear during you/your child's visit, experience going

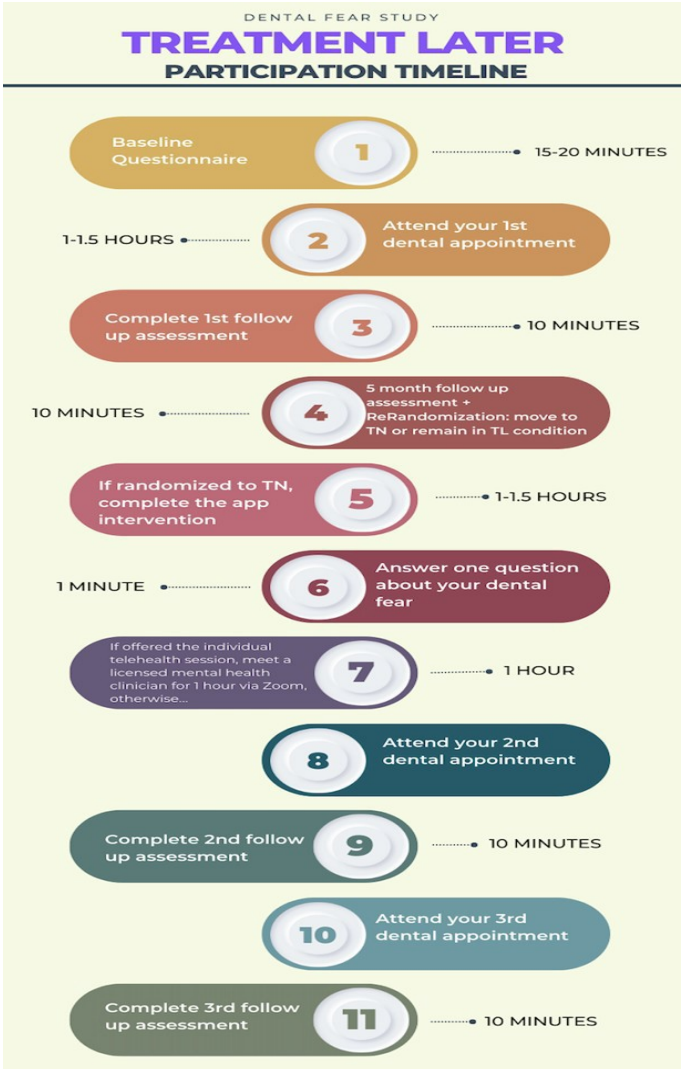
to the dentist, oral health, and quality of life. You/your child will also be sent a link and asked to fill out the same questionnaire following you/your child's next dental visit (approximately 6 months later).

If you/your child are assigned to the ***TL condition*** at the start of the study

- At some point during the month before you/your child's scheduled dental visit, you/your child will be asked to take part in a phone interview with a member of this study team about you/your child's experiences with dentists and what you/your child would like to see improve. This will take 15-20 minutes.

- You/your child will then go to you/your child's scheduled dental visit. After your/your child's dental visit, you/your child will be sent a secure link to complete a brief (~10 min) follow-up questionnaire about your/your child's dental fear during your/your child's visit, experience going to the dentist, oral health, and quality of life. You/your child will be sent secure links to repeat those same questionnaire 5 months after your/your child's dental visit, and following your/your child's next two dental visits (V2, and V3).

- After the 5-month questionnaire, you/your child may be rerandomized to the ***TN condition***. In this instance, you/your child will be asked to complete the mobile app intervention, the 1:1 telehealth session, or both, as described above. You/your child will then attend you/your child's next 2 scheduled dental appointments, and complete the same brief questionnaire as previously mentioned.



While in this study, you/your child will also be asked to give consent to request access to you/your child's administrative attendance records from you/your child's dentist's office for up to 23 months from the date you/your child sign this consent. We are interested in tracking the number of appointments attended, canceled, or no-showed among our participants during the period following study participation.

☐ Yes, I provide my consent to the researchers to contact my dentist _____ and have my appointment attendance records (number and type of appointments attended, canceled, no-showed).

☐ No, I **do not** provide my consent to the researchers to contact my dentist _____ and have my appointment attendance records (number and type of appointments attended, canceled, no-showed).

[If 'No' is selected]

☐ I will contact my dentist and send my appointment attendance records (number and type of appointments attended, canceled, no-showed) to the study team via secure link to NYU's HIPAA- and HITECH-compliant version of Dropbox for Business.
**However, if records are not received within 6 months of the researcher's request, then **YES, I provide my consent** to the researchers to contact my dentist and have my appointment attendance records (number and type of appointments attended, canceled, no-showed).

If you/your child are part of the 1:1 telehealth session or the 15-20 minute scheduled interview for the TL participants, you/your child will be to asked give consent for the session to be audio and/or video recorded on the Zoom platform. Sessions will be recorded so that the study supervisor can make sure the study clinicians and team are providing good intervention. Only select study supervisors will have access to the A/V recordings, which will be stored under the initials of the study clinician and a number (in the order of participants that the clinician has seen) in a password-protected folder. None of you/your child's information will be associated with the recorded file, which cannot be linked back to you/your child. All study recordings will be destroyed 5 years after the final data analyses are completed and the manuscript published, and will not be used for any additional purposes without you/your child's explicit permission (see below).

☐ If I receive the 1:1 telehealth session or the 15–20-minute scheduled interview, I provide my consent to the researchers to record it and store it in a secure password-protected file by clinician ID for monitoring and supervising the mental health clinician in their delivery of the dental fear treatment.

**Optional**: I additionally give the researchers permission to store my recorded session without identifiers for future research (e.g., to help with questions about specific symptoms of dental fear or negative dental experiences).

☐ Yes ☐ No **Initial here**: _____

Any identifiable information collected in REDCap to carry out this research study will not be used or distributed for future research studies.

## 5. What are the possible risks or discomforts?

There are some risks from being in this study. The mobile app intervention and 1:1 telehealth session present minimal risk to participants. You/your child may experience some distress when answering questions about you/your child's dental fear or while using the app (if applicable). However, you/your child can stop participation at any point in the study, and skip questions you/your child do not want to answer.

There is also a risk of potential loss of confidentiality. We will minimize this risk by assigning you/your child a participant number and not identifying you/your child by name or collecting any other information that would make it possible for anyone to identify you/your child. Any information used for app registration (i.e., your email) will be kept in a password-protected secure file and will be destroyed when data collection has been completed. leted. The mobile app does not collect any other personal or sensitive data. It tracks only user metrics (how much of the app has been completed, how many modules done, how much time spent using the app, and which multiple-choice response options were chosen to answer questions). The recorded 1:1 sessions, for whom they are applicable, will be saved in a password- protected secure file with no ties to you/your child (identifiable only by the clinician who conducted the session and the number of participants they have seen), accessible only by a handful of supervisory study staff (e.g., study treatment supervisor, clinically licensed study investigator).

Additionally, throughout this study, all data you/your child provide is collected and stored in one place (the REDCap system) which has significant security and encryption to protect against risks of loss of confidentiality. Only IRB-certified members of the research team will have access to you/your child's data. Any identifying information (names, phone numbers) will only be collected for consent and recontact purposes and will be maintained exclusively in REDCap.

## 6. What if new information becomes available?

During the course of this study, we may find more information that could be important to you/your child. This includes information that might cause you/your child to change your/your child's mind about being in the study. We will notify you/your child as soon as possible if such information becomes available.

## 7. What are the possible benefits of the study?

You/your child may or may not benefit from being in this study. Depending on if you/your child are assigned to receive a dental fear intervention and/or 1:1 telehealth session, you/your child may experience less fear and a greater ability to tolerate you/your child's dental visits. The information you/your child provide will help us learn how to improve our stepped-care treatment for dental fear.

## 8. What other choices do I have if I do not participate?

The alternative to participating in this study is not participating. You/your child will not be penalized for not participating in this research and you/your child may stop at any time. You/your child's standard dental care will not be affected if you/your child decide not to participate or discontinue you/your child's participation at any time.

## 9. Will I be paid for being in this study?

You/your child can be paid up to $100 in Amazon eGift Cards for you/your child's participation in the study. Compensation will be based on the number of visits you/your child are eligible for and complete. You/your child will receive $20 for each questionnaire you/your child complete during this study.

## 10. Will I have to pay for anything?

There are no additional costs to you/your child from being in this study. You/your child can download and use the *DentalFearless* mobile app at no cost to you/your child. If you/your child are offered the individual 1:1 telehealth session, you/your child's session will be paid for by the study.

## 11. Financial Disclosure

NYU Langone Health maintains a financial disclosure process by which researchers must disclose any personal financial interest that may be related to the research. One or more of the researchers involved

in this study is an inventor of the DentalFearless app that is owned by NYU and will be used to facilitate this study. As a result of the intellectual property rights, these researchers and NYU may benefit if the results of this study are favorable.

If you/your child would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-404-4089. If you/your child would like more information, please ask the researchers, the study coordinator, or the CIMU at 212-404-4079.

## 12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you/your child think you/your child have been injured as a result of taking part in this research study, tell the principal investigator as soon as possible. The principal investigator's name and phone number are listed at the top of page 1 of this document, as well as the name and phone number for the emergency contact.

If such complications arise, the study investigator will assist you/your child in obtaining appropriate treatment, but this study does not provide financial assistance for related costs. There are no plans for NYU Langone Health or NYU College of Dentistry to pay you/your child or give you/your child other compensation for the injury. You/your child do not give up you/your child's legal rights by signing this form.

## 13. When is the study over? Can I leave the study before it ends?

This study is expected to end after all participants have completed all assessments (questionnaires) and all attendance information has been collected. If you/your child decide to participate, you/your child are free to leave the study at any time. Leaving the study will not interfere with you/your child's current or future dental or health care.

## 14. How will you protect my confidentiality?

You/your child's medical information is protected health information, or "PHI," and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act (HIPAA). You/your child have a right to access information in you/your child's research record. In some cases, when necessary to protect the integrity of the research, you/your child will not be allowed to see or copy certain information relating to the study while the study is in progress, but you/your child will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Medical or dental information will not be created by this research study or become a part of you/your child's medical or dental record.

**Certificate of Confidentiality**

To help us further protect you/your child's confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you/your child.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without you/your child's consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you/your child in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without you/your child's consent. However, disclosure, without you/your child's consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

## 15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you/your child and relates to you/your child's past, present and future physical and mental health conditions. We are asking for your/your child's permission (authorization) to use and share your/your child's health information with others in connection with this study. In other words, for purposes of this research, including conducting and overseeing the study.

You/your child's treatment outside of this study, payment for you/your child's health care, and you/your child's health care benefits will not be affected even if you/your child do not authorize the use and disclosure of you/your child's information for this study.

**What information may be used or shared with others in connection with this study?**
All information in you/your child's research record for this study may be used and shared with those individuals listed in this section. Administrative information from your/your child's medical record will be shared by you/your child's dentist with the study personnel (with your/your child's signed consent above). This includes appointments kept, canceled, rescheduled, and no-showed, for up to 23 months from the date of this consent form.

**Who may use and share information in connection with this study?**

The following individuals may use, share, or receive you/your child's information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- The study sponsor: New York University
- Governmental agencies responsible for research oversight

You/your child's information may be re-disclosed or used for other purposes if the person who receives you/your child's information is not required by law to protect the privacy of the information.

**What if I do not want to permit to use and share my information for this study?**
Signing this form is voluntary. You/your child do not have to give us permission to use and share your/your child's information, but if you/your child do not, you/your child will not be able to participate in this study.

**Can I change my mind and withdraw permission to use or share my information?**

Yes, you/your child may withdraw or take back you/your child's permission to use and share you/your child's information at any time for this research study. If you/your child withdraw you/your child's permission, we will not be able to take back information that has already been used or shared with others. To withdraw your/your child's permission, send a written notice to the principal investigator for the study noted at the top of page 1 of this form. If you/your child withdraw you/your child's permission, you/your child will not be able to stay in this study.

**How long may my information be used or shared?**

You/your child's permission to use or share your/your child's personal health information for this study will never expire unless you/your child withdraw it. You/your child's information may be re- disclosed or used for other purposes if the person who receives you/your child's information is not required by law to protect the privacy of the information.

**What if I do not want to give permission to use and share my information for this study?**
Signing this form is voluntary. You/your child do not have to give us permission to use and share your/your child's information, but if you/your child do not, you/your child will not be able to participate in this study.

## 16. The Institutional Review Board (IRB) and how it protects you/your child.

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU Langone Health IRB Office number is (212) 263-4110. The NYU Langone Health IRB is made up of doctors, nurses, non-scientists, and people from the community.

## 17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you/your child have questions, concerns, or complaints regarding you/your child's participation in this research study, or if you/your child have any questions about you/your child's rights as a research subject, you/your child should speak with the Principal Investigator or Emergency Contact person listed on top of page 1 of this document. If a member of the research team cannot be reached or you/your child want to talk to someone other than those working on the study, you/your child may contact the NYU Langone Health IRB at (212) 263- 4110.

## 18. Research with Applications, Software & Novel Technology

This study will use a *Dental Fearless* mobile application to gather information for the researchers as part of this study. This mobile application is provided by Virtually Better, Inc and there are terms of use that the vendor requires of all users. You/your child will need to review the vendor's terms of use and privacy policy.

The vendor may retain some of the data collected through the mobile application even after the study ends. If you/your child does not want this data collection to continue by the vendor after the study ends, you/your child will need to uninstall/discontinue use of the *Dental Fearless* mobile application. Even after you/your child have uninstalled the application, the vendor may still retain you/your child's data so make sure to read the privacy policy and EUA/TOS. The research team can help explain how to do this.

virtuallybetter.com/documents/VBI_PrivacyPolicy.pdf

https://apps.apple.com/tz/app/dental-fearless/id1570306109

**When you sign this form**, you are agreeing to take part in this research study as described to you/your child. This means that you/your child have read the consent form, you/your child's questions have been answered, and you/your child have decided to volunteer.

| Name of Subject (Print) | Signature of Subject | Date |
|---|---|---|
| Name of Person Obtaining Consent (Print) | Signature of Person Obtaining Consent | Date |