ObvioHealth
The Digital Revolution Gets Clinical

STATISTICAL ANALYSIS PLAN

Study Number	OBVIO-DAN-003
Title	A pilot study evaluating sleep, stress, and infant nutrition using a chatbot with parents of preterm and full-term infants
Sponsor	Danone
Country	United States
Date	11 APR 2019
Version Number	1.0

STATISTICAL ANALYSIS PLAN SIGNATURE PAGE

We, the undersigned, have reviewed and approved this SAP including the appendices and TLF Shells.

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Table of Contents

1. Abbreviations

Abbreviation	Definition
CRO	Contract Research Organization
eCRF	Electronic Case Report Form
ICF	Informed Consent Form
ICU	Intensive Care Unit
IRB	Institutional Review Board
PI	Principal Investigator

2. Synopsis

Study Title	A pilot study evaluating sleep, stress and infant nutrition using a chatbot with parents of preterm and full-term infants
Study Objectives	**Primary Objective:** To generate real-life, in-home data from parents with infants (preterm and full-term) on sleep, stress, and infant nutrition via the study chatbot **Secondary Objective:** To investigate differences in data obtained from parents of preterm infants versus data obtained from parents of full-term infants on sleep, stress, and infant nutrition **Exploratory Objective:** To evaluate the usability of ClaimIt, the study chatbot, and chatbot tools in general, among this population
Study Design	An observational study of parents with infants (preterm and full-term)
Study Observation Duration	28 days per family
Country of Implementation	Singapore
Study Population	• 20 parents with healthy preterm infants (born at <37 weeks of gestation), age 0-6 months and discharged from the hospital at time of enrollment • 20 parents with healthy full-term infants (born at ⩾37 weeks of gestation), age 0-6 months and discharged from the hospital at time of enrollment

Inclusion Criteria	**Subjects (parent and infant) must meet the following criteria:** • Healthy infants (preterm and full-term) must be 0-6 months of age at time of enrollment • Infants must be at home (discharged from the hospital) at time of enrollment • Informed consent from parent whose age is ⩾21 years • Parent must be proficient in the English language • Parent must be able to comply with the required study tasks, as per PI's judgment • In-home access to reliable internet connections; a mobile device suitable for electronic communication

Exclusion Criteria	**Infant must not meet any of the following criteria:**
	• Known to have current or previous illnesses/conditions which could interfere with the study outcome (per PI's clinical judgment)
	• Must not be currently participating in any other clinical study
	Parent must not meet any of the following criteria:
	• Must not be known to have a significant medical condition that might interfere with the study (per PI's clinical judgment) that meets one of the following criteria:
	  ○ Presence of current mental illness or history of mental illness
	  ○ Any acute or chronic illness that makes the parent unsuitable for the study based on the PI's judgment
	• Must not be a single parent
	• Inability of the parent to comply with the study protocol or PI's uncertainty about the willingness or ability of the parent to comply with the protocol requirements

Endpoints	**Primary:** Obtaining records of sleep, stress, and infant nutrition from parents of infants (preterm and full-term) through interaction with the study chatbot **Secondary:**

	Comparison of the data obtained from parents of preterm infants and parents of full-term infants on sleep, stress, and infant nutrition **Exploratory:** An evaluation of the usability of ClaimIt, the study chatbot and chatbot tools in general, among this population
Study Implementation	**Prescreening** • Participants (parents and infants [preterm or full-term]) will be recruited by study team personnel in the Department of Neonatology at KK Women's and Children's Hospital • Upon successfully fitting the basic eligibility criteria, the parent will be provided: ○ Informed Consent Form (ICF) for review ▪ The parent will have the opportunity to ask questions and receive answers from study team personnel ○ Access to the ClaimIt app along with the following information: ▪ Overview of trial tasks and relevant notifications ▪ ClaimIt navigation instructions: How to interact with the ClaimIt app during the study period ▪ Additional study details & instructions ▪ All relevant contact information that may be required during the study **Screening and Enrollment**

	• Upon signing the ICF, the parent will be asked to respond to a detailed eQuestionnaire (Appendix I) to assess eligibility • If all the inclusion and none of the exclusion criteria are satisfied, the PI will enroll the subjects into the study • Upon enrollment, the parent will be provided full access to the study chatbot along with the following information: o How to connect to the study chatbot o Overview of trial requirements & parameters o The Chatbot navigation: How to interact with the study chatbot during the 28-day period o Overview of notifications related to trial activities o Additional study details & instructions **Data Collection Period** • The parent will be asked to regularly interact with the study chatbot on three (3) topics, three (3) days a week (suggested schedule: M, W, F) for 28 days • Through regular interaction with the study chatbot, records of parents' sleep, stress, and infant nutrition will be obtained **End of Study** • At the end of the 28-day data collection period, the parent will be asked to complete an eQuestionnaire about the usability of the study chatbot and ClaimIt (Appendix II)
Statistical Considerations	A sample size of 40 parents and their infants is estimated with the following considerations: • Descriptive summary statistics for the categorical and quantitative data will be reported

	• Expected dropout rate of ⩽10 subjects (if the dropout threshold of 10 is reached, up to 10 additional subjects may be replaced at the sponsor's discretion) • A subject will be considered to have dropped out if they are determined to be non-compliant
Statistical Analysis	The follow statistical analyses will be performed: • Qualitative analysis of free-form Chatbot data using RQDA statistical analysis package in R. • Descriptive statistical analysis of Usability of Chatbot and ClaimIt eQuestionnaire data

3. Revision History

Version	Version date	Summary of modifications
0.1	13JUN2018	Initial draft
1.1	15AUG2018	Signature Page, Section 9.1
0.2	16OCT2018	Revisions per Danone's review; change to version to conform with Obvio versioning convention.
0.3	21MAR2019	SAP reverted back to v0.2 for simplification of qualitative analysis; comments from ST addressed.
0.4	04APR2019	New definition for analysis data sets; Final comments addressed.
1.0	08APR2019	Additional Danone comments addressed – First executable version.

4. Background

An estimated 15 million infants, slightly more than 1 in 10, are born preterm each year worldwide.[1] Approximately 60% of those are born in South Asia and sub-Saharan Africa.[1] As the leading cause of death in children under the age of 5 years, about one million preterm infants die each year worldwide due to preterm birth complications, with a significantly greater mortality rate in low-income countries compared to high-income countries.[1] Consequently, given the significance of meticulous care required for the preterm infants, healthcare providers and parents play a central role in assuring proper care of these vulnerable children.

Parental involvement in caring for infants can lead to anxiety, worry, and psychological distress. In a follow-up clinic evaluation of parents and their premature infants, many reported parental concerns about medical and developmental outcomes were unsupported by their child's diagnosis.[2] In a study done with parents of late-preterm infants (≥34 to <37 weeks gestation), mothers reported significantly more stress than fathers on the Parent Stress Index (PSI-3), a tool designed for the early identification of parental and familial characteristics that fail to foster normal development and function in children.[3] An assessment of maternal psychological distress in singleton versus multiple-birth preterm infants found that mothers of multiples had greater posttraumatic stress symptoms, anxiety at discharge and depressive symptoms at six months as compared to mothers of singletons.[4] Among mothers of school-aged children who were born late preterm and admitted to an intensive care unit (ICU), there was a significant 18-fold increase in total stress compared to stress among mothers of full-term children.[5] In a parallel study group involving mothers of school-aged children who were born late preterm, but not admitted to the ICU, there was a

24-fold increase in total stress when compared to the mothers of full-term children.[5] Overall, multiple studies have demonstrated that parental stress, anxiety, and psychological distress are not only short-term problems when caring for a preterm infant, but may also have long-lasting effects.

In this study, data will be collected comparing infant nutrition, stress, and sleep in parents of both preterm infants and full-term infants (after they have been discharged from the hospital), using a chatbot application. A chatbot is defined as, "an instant messaging account that is able to provide services using instant messaging frameworks with the aim of providing conversational services to users in an efficient manner." In short, a chatbot can respond to a user as though they are communicating with another person via instant messenger, except there is a computer on the other end.[6] The chatbot application in this study is designed to provide an interactive tool for the parents to provide input on infant nutrition and parent stress and sleep.

5. Objectives

5.1 Primary Objective

To generate real-life, in-home data from parents with infants (preterm and full-term) on sleep, stress, and infant nutrition via the study chatbot.

5.2 Secondary Objective

To investigate differences in data obtained from parents of preterm infants versus data obtained from parents of full-term infants on sleep, stress, and infant nutrition.

5.3 Exploratory Objective

To evaluate the usability of ClaimIt, the study chatbot, and chatbot tools in general, among this population.

6. Trial Design

This is an observational study of 40 parent and infant pairs (20 parents of preterm infants, 20 parents of full-term infants) residing in Singapore.

6.1 Trial Endpoints

Primary Endpoint

Obtaining records of sleep, stress, and infant nutrition from parents of infants (preterm and full-term) through interaction with the study chatbot

Secondary Endpoint

Comparison of the data obtained from parents of preterm infants and parents of full-term infants on sleep, stress, and infant nutrition obtained via the study chatbot

Exploratory Endpoint

An evaluation of the usability of ClaimIt, the study chatbot and chatbot tools in general, among this population.

6.2 Study Population

6.2.1 Subject Inclusion Criteria

- Healthy infants (preterm [born at <37 weeks of gestation] and full-term [born at ⩾37 weeks of gestation]), 0-6 months of age at time of enrollment
- Infants must be at home (discharged from the hospital) at time of enrollment
- Informed consent from the parent (whose age is ⩾21 years)
- Parent must be proficient in the English language
- Parent must be able to comply with the required study tasks, as per PI's judgment
- In-home access to reliable internet connections and a tablet and/or mobile device suitable for electronic communication

6.2.2 Subject Exclusion Criteria

To be considered for enrollment, the subjects must not meet any of the exclusion criteria listed below:

Infants:

- Known to have current or previous illnesses/conditions which could interfere with the study outcome, as per PI's clinical judgment
- Must not be currently participating in any other clinical study

Parent of infants:

- Must not be known to have a significant medical condition that might interfere with the study (per PI's clinical judgment) that meets one of the following criteria:
  - Presence of current mental illness or history of mental illness
  - Any acute or chronic illness that makes the parent (subject) unsuitable for the study based on the PI's judgment
- Must not be a single parent
- Inability of the parent to comply with the study protocol or PI's uncertainty about the willingness or ability of the subject to comply with the protocol requirements

6.2.3 Subject Withdrawal Criteria

Subjects may be withdrawn from the study at any time for any reason, including but not limited to:

1) At their request or the request of the legally authorized representative.
2) If, in the PI's opinion, continuation in the study would be detrimental to the parent or infant's well-being.
3) Non-compliance (failure to complete five [5] or more consecutive sessions), at the discretion of the PI (a situation where the parent consistently does not adhere to the study procedures).

4) Protocol deviation(s) which, in the opinion of Sponsor, warrant discontinuation from study (e.g., violation of inclusion and/or exclusion criteria).

A dropout of ≤10 families is built into the estimated total sample size. If the dropout threshold of 10 is reached, up to 10 additional participants may be replaced at the sponsor's discretion. The PI must make every effort to contact parents that are lost to follow-up. Attempts to contact the parent must be documented in the family's record (e.g., dates and times of attempted telephone/email contact).

The number and percentage of subjects who withdraw early and their reasons for withdrawal will be presented in a table and the equivalent of a CONSORT flow diagram.

The following information will be documented in the mother and infant/toddler's record in the event of a subject's withdrawal from the study:

I. Date of withdrawal
II. Reasons for withdrawal

Even if consent is withdrawn, all data that were acquired before consent was withdrawn will be maintained.

6.3 Centers

Participants will be recruited through the Department of Neonatology at KK Women's and Children's Hospital. After the screening visit, infants and parents will not be required to visit a physical trial site (unless reconsent is required). Communication between parents and study personnel will be conducted via the ClaimIt platform and/or over the telephone or email messaging, as appropriate.

7. Execution of the Trial

7.1 Chatbot Interactions During Study Period

The parent will be asked to interact with the study chatbot three times a week (e.g., Monday, Wednesday and Friday [suggested schedule]) over a maximum 28-day period. During each of those interactions, they will be asked to interact on all three topics: sleep, stress, and infant nutrition. Reminder notifications will be sent via ClaimIt for any parent that does not interact with the chatbot per protocol.

The maximum number of interactions per subject pair is 12 (in total).

7.2 Data Collection

Chatbot transcripts will be created based on each interaction between the parent and study chatbot.

eCRFs will be completed by the parent for their infant based on data from:

- the Screening eQuestionnaire
- the end-of-study Usability eQuestionnaire

7.3 Compliance

Compliance with the study expectations will be monitored through the study chatbot's regular use and reported as follows:

- Compliant: Defined as having completed a total of 7 or more interactions with the study chatbot in the 4-week study period

  Note: If only seven (7) sessions are completed with the study chatbot, the five (5) missing interactions must not be consecutive

- Non-compliant: Defined as the failure to complete five (5) or more consecutive sessions in the 4-week study period

Subjects may be withdrawn from the study in the event of non-compliance.

7.4 End of Study

At the end of the study, the parent will be asked to complete an eQuestionnaire to assess and comment on the usability of ClaimIt, the study chatbot and chatbot tools in general (Appendix II). Access to the study chatbot will be discontinued, and the study team may contact the parent if there are any outstanding study related queries.

7.5 Application Description

The study chatbot is an interactive, conversational application where the parent can initiate a conversation with the chatbot, and it will respond appropriately. In certain instances, the study chatbot may also initiate a conversation with parent. The application converses with the user through the messaging platform. Transcripts of the chatbot conversations will be accessed and reviewed by the study team.

Completion of the Screening and Usability eQuestionnaires will occur via the ClaimIt app for each of the parents. The ClaimIt app is a mobile application available to subjects during their period of enrollment so they can perform specific study-related tasks and receive and transmit communications from and to the CRO staff.

7.7 Computerized Edit Checks

The database will incorporate the needed programmed edit checks to help ensure quality data. Messages to the parent may be generated automatically to alert him/her to any entry error or protocol non-compliance.

8. Statistical Analysis

8.1 Sample Size Calculations

A sample size of 40 subjects is estimated under the following considerations:

- Descriptive summary statistics for the categorical and quantitative data will be reported
- Expected dropout rate of ⩽10 subjects (if the dropout threshold of 10 is reached, up to 10 additional participants may be replaced at the sponsor's discretion)
- A subject will be considered to have dropped out if they are determined to be non-compliant; however, qualifying chatbot interactions will be included in ITT.

8.2 Datasets to be Analyzed

8.2.1 Intent-to-treat (ITT)

All enrolled participants in accordance with the Intent-to-treat (ITT) principle.

8.2.2 Full Analysis Set (FAS)

All ITT participants who have completed at least one topic (Sleep, Stress, and/or Nutrition).

8.2.3 Per Protocol (PP)

All FAS participants who have no protocol violations (i.e. participants who have completed at least seven interactions – protocol deviations are permitted and reportable) and remained in the study for the full data collection period.

Protocol violations and deviations and study completion data will be evaluated through statistical analysis.

8.3 Primary Endpoints

This study's primary objective is to generate real-life, in-home data from parents with infants (preterm and full-term) on sleep, stress, and infant nutrition via the study chatbot. The primary endpoint(s) are records of sleep, stress, and infant nutrition from parents of infants (preterm and full-term) through interaction with the study chatbot.

8.4 Secondary Endpoints

The study's secondary objective is to investigate differences in data obtained from parents of preterm infants versus data obtained from parents of full-term infants on sleep, stress, and infant nutrition.

In order to evaluate these differences, data obtained through RQDA (see 8.3.1 above) will be categorized in order to develop outcomes and/or measures that can be analyzed between groups. The exact nature of these secondary endpoint variables is unclear as of the development of this SAP; however, said variables will be established in a written agreement with Danone's Chatbot team.

Tables, listings, and figures pertaining to secondary endpoints are grouped by analysis data set (FAS and PP) in the TLF shells.

8.4.1 Qualitative Data Analysis

The RQDA package (housed within the R statistical analysis software) will be used to perform the analysis of the free-text data stream that will be produced from Chatbot. As a background, RQDA is a R package for Qualitative Data Analysis, a free qualitative analysis software application (BSD license). It works on Windows, Linux/FreeBSD and Mac OSX platforms. RQDA is an easy to use tool to assist in the analysis of textual data. At the moment it only supports plain text formatted data. All the information is stored in a SQLite database via the R package of RSQLite. The GUI is based on RGtk2, via the aid of gWidgetsRGtk2. It includes a number of standard Computer-Aided Qualitative Data Analysis features. In addition, it seamlessly integrates with R, which means that a) statistical analysis on the coding is possible, and b) functions for data manipulation and analysis can be easily extended by writing R functions.

RQDA allows the user to define certain word pairings, coding schemes, etc. that can be used to pick out trends within the free text. The user can isolate one free text document or can analyze across as many documents as are necessary. For the

purposes of this study, we will analyze trends within among/between subjects. Sample output for the RQDA package is found in Appendix III.

8.5 Exploratory Endpoints

The study's exploratory endpoint is an evaluation of the usability of ClaimIt, the study chatbot and chatbot tools in general, among this population.

To accomplish this analysis, descriptive statistical analysis will be performed on each question of the Usability of Chatbot and ClaimIt eQuestionnaire. Questions will be analyzed for frequency and, in the case of questions that are based on Likert Scales, univariate distributions (mean, median, standard deviation, etc.).

Question 9 through 14 of the questionnaire are open-ended. Qualitative analysis will be performed on these questions where possible in order to obtain the frequencies of certain response patterns. In the case of individual answers (that do not follow a pattern) such will be presented in list form.

Tables, listings, and figures pertaining to exploratory endpoints are grouped by analysis data set (FAS and PP) in the TLF shells.

8.6 Interim Analysis

No interim analysis is planned.

8.7 Tables, Figures, and Lists

8.7.1. Baseline characteristics and Usability Questionnaire

Tables of outputs from the proposed analysis are detailed in the TLF Deliverable Shell (see Section 10.2 for details). They are described below.

Table 1 outlines the baseline characteristics of both the respondents and infants in question. The mean age for respondents is reported with a standard deviation. Frequencies and percentages are reported for the following age categories: 21-25,

26-30, 31-35, 36-40, 41-45, and older than 45. Gender is reported for respondents as male and female.

Mean age for infants is also reported with standard deviations. Frequencies and percentages are reported for the following age categories: newborn (<1 month), 1 month, 2 months, 3 months, 4 months, 5 months, 6 months. Frequencies and percentages are given for both gestational age categories (premature (<37 weeks) and full-term (≥37 weeks)). Gender is also reported for infants as male and female.

Table 2 record the mean and standard deviation of Likert score responses as well as frequencies and percentages for questions 1, 2, 3, 4, 7, 8, 15, and 16 of the Usability of Chatbot and ClaimIt eQuestionnaire. Mean scores and standard deviations are reported as numbers to two decimal places. For example, if thirty of the forty mothers answered question one of the questionnaire as “Very easy” while ten of the participants answered “Easy”, then the mean response value for that question would be 4.75 with a standard deviation of 0.44.

Table 3 reports the frequencies and percentages of responses to questions 5 and 6 of the Usability of Chatbot and ClaimIt eQuestionnaire which address whether or not the study chatbot malfunctioned (Yes or No) and whether or not the ClaimIt app malfunctioned. For each software malfunction, the participant is asked to report what happened. Their responses are recorded for all chatbot malfunctions in Table 4 and all ClaimIt malfunctions in Table 5.

Tables 6-11 report open-ended answers to questions 9, 10, 11, 12, 13, and 14 of the Usability of Chatbot and ClaimIt eQuestionnaire. As nearly all answers to open-ended questions will be unique, all answers of a like theme will be recorded (for all intents as purposes) as the same answer. For example, if one respondent answers question 13 (“What did you like the most about the ClaimIt app?”) by saying “I thought the app was easy to use”, another answers “Easy to use”, and another answers “Ease of use”, then this answer will be reported as “Easy to use” (for example) with a frequency of three

(3). Any answers that are completely unique will be reported as such with a frequency of one (1).

8.7.2. Analysis of Scripts

A series of analyses will be performed based on the Nutrition, Sleep, and Stress scripts administered to each participant. Results will be presented through figures and tables as appropriate.

Figures 1-21 are listed in the TLF deliverable shell. All figures will be in presented as bar charts and will provide enumerations of the categories detailed in their respective titles. Categorizations and subdivisions within each table are indicated by the word "by" in the title.

Tables 12-28 will present response frequencies to all open-ended questions within the scripts administered to each participant. Answers of the same theme will be compiled and presented as frequencies of the same answer as explained above in the example for Tables 6-11. Again any answers that are completely unique will be listed with a frequency of one (1).

All results from the analysis of chatbot scripts will be stratified by gestational maturity (preterm versus full-term) upon presentation.

9. Quality Control

9.1 Data and Output Quality Checks

All coding and results produced as part of this SAP will be reviewed for correctness and reproducibility via code review on primary, secondary, exploratory and baseline characteristics.

Parallel coding is not performed; however, all code developed by the Biostatistics Department is reviewed and agreed upon iteratively for correctness and to ensure that all outputs meet the sponsor's specifications. All results are then reviewed by at least two members of the senior management team for quality control and interpretability.

Any issues identified during the code review will be documented and corrected until there are no issues. This will be done in order to safeguard against any errors, omissions, or deviation from the SAP. At the end of analysis, the raw output files and the final analysis datasets should be available and stored.

10. Reporting

10.1 Clinical Study Report

A Clinical Study Report will be developed and provided by ObvioHealth after the following have occurred: database lock, completed statistical analysis, and completed and client-approved TLF deliverable (through executed Tables, Listings, and Figures Deliverable Finalization Form). The report will review study background and methodology and will include all required results including all tables, listings, and figures agreed upon in the TLF Deliverable Shell (see Section 10.2 immediately below).

10.2 TLF Deliverable Shell

In conjunction with the finalized SAP, ObvioHealth and Danone will agree upon a set of tables, figures, and listings that will be provided as part of the final study deliverable – the TLF Deliverable Shell.

The TLF Deliverable Shell will consist of a set of spreadsheets (or in other words, a workbook) that houses the empty versions of all tables and listings for this study. The final worksheet in this workbook will be a list of figures to be delivered.

An executed SAP constitutes a written agreement on the TLF Deliverable Shell. As such, the most recent TLF Deliverable Shell will be versioned to 1.0 and considered final. Any additions to the final TLF Deliverable Shell after execution will require an amendment to the SAP and potential changes to the study contract.

11. References

1. World Health Organization. (2017). *Preterm birth.* 2017 November [Accessed February 2, 2018]; Fact Sheet. Available from: http://www.who.int/mediacentre/factsheets/fs363/en/.
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3. Mughal, M.K., et al. (2017). *Parenting stress and development of late preterm infants at 4 months corrected age*. Res Nurs Health, 2017. **40**(5): p. 414-423.
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5. Polic, B., et al. (2016). *Late preterm birth is a strong predictor of maternal stress later in life: Retrospective cohort study in school-aged children.* J Paediatr Child Health, 2016. **52**(6): p. 608-13.
6. Rahman, A. M., Al Mamun, A., & Islam, A. (2017). Programming challenges of chatbot: Current and future prospective. *Humanitarian Technology Conference* (R10-HTC), 2017 IEEE Region 10: p. 75-78.

12. Appendices

Appendix I: Usability of Chatbot and ClaimIt eQuestionnaire

The following is a questionnaire is for you to provide feedback on your interactions with the chatbot. Please pick the best answer.

1. Please rate the study chatbot's overall ease of use on a scale of 1 to 5:

   (Very Difficult) 1 2 3 4 5 (Very Easy)

2. Please rate the ClaimIt application's overall ease of use on a scale of 1 to 5:

   (Very Difficult) 1 2 3 4 5 (Very Easy)

3. How satisfied were you with your interactions with the study chatbot?

   (Very Dissatisfied) 1 2 3 4 5 (Very Satisfied)

4. How satisfied were you with your interactions with ClaimIt?

   (Very Dissatisfied) 1 2 3 4 5 (Very Satisfied)

5. Did the study chatbot malfunction?

   a. Yes (will be asked a follow-up question)
   b. No

   (If Yes) How did the study chatbot malfunction? *[Open-ended question]*

6. Did ClaimIt malfunction?

   a. Yes (will be asked a follow-up question)

   b. No

   (If Yes) How did ClaimIt malfunction? [Open-ended question]

7. How likely are you to consider using a chatbot application as an interactive tool to provide input on similar topics?

   (Not at all Likely) 1 2 3 4 5 (Very Likely)

8. How would you rate the length of interactions you had with the study chatbot?

   (Too Long) 1 2 3 4 5 (Easily Manageable)

9. What did you like the least about the study chatbot? _____ *[Open-ended question]*

10. What did you like the most about the study chatbot? _____ *[Open-ended question]*

11. Do you have any other comments about the study chatbot that you would like the investigators to know? _____ *[Open-ended question]*

12. What did you like the least about the ClaimIt app? _____ *[Open-ended question]*

13. What did you like the most about the ClaimIt app? _____ *[Open-ended question]*

14. Do you have any other comments about the ClaimIt app that you would like the investigators to know? _____ *[Open-ended question]*

15. How worried were you about sharing your data with the study chatbot?

    (Not at all worried) 1 2 3 4 5 (Very worried)

16. How likely would you be to use a chatbot tool like this in real life to get access to information and reassurance if you could?

    (Not at all likely) 1 2 3 4 5 (Very likely)

    Why or why not? *[Open-ended question]*

Appendix II: Sleep Script

<table>
<tr><td colspan="9">How did you sleep last night?</td></tr>
<tr><td colspan="4">Good</td><td colspan="5">Not well</td></tr>
<tr><td colspan="4"></td><td colspan="5"></td></tr>
<tr><td colspan="2"></td><td colspan="2"></td><td colspan="3"></td><td colspan="2"></td></tr>
<tr><td colspan="4">Thanks for sharing that. How many total hours of sleep did you get last night?
[Collect open ended numerical response and filter into below categories]</td><td colspan="5">Thanks for sharing that. How many total hours of sleep did you get last night?
[Collect open ended numerical response and filter into below categories]</td></tr>
<tr><td><7 hours</td><td colspan="2">≥7 hours</td><td>I don’t know</td><td><7 hours</td><td colspan="2">≥7 hours</td><td>I don’t know</td></tr>
<tr><td rowspan="3">I’m glad you still feel well-rested. Did anything affect your sleep?</td><td colspan="2" rowspan="3">That is a good amount of sleep! Did anything bother you about your sleep?</td><td>That’s ok, I only need an estimate.</td><td rowspan="3">What do you think affected your sleep?</td><td colspan="2" rowspan="3">That is a good amount of sleep. Why do you feel like you didn’t sleep well? Did anything bother you about your sleep?</td><td>That’s ok, I only need an estimate.</td></tr>
<tr><td>[Collect open ended numerical response]</td><td>[Collect open ended numerical response]</td></tr>
<tr><td>Please share what may have affected your sleep last night.</td><td>Please share what may have affected your sleep last night.</td></tr>
<tr><td colspan="9">[All questions lead to these responses]</td></tr>
<tr><td colspan="3" rowspan="2">I went to bed too late.</td><td>I woke up during the night.</td><td colspan="3" rowspan="2">I woke up too early.</td><td rowspan="2">Other</td><td rowspan="3">Nothing affected my sleep.
[Skip to question below]</td></tr>
<tr><td>Sorry to hear that, do you remember how often you woke up? [Collect open ended response]</td></tr>
<tr><td colspan="3">Sorry to hear that, what in particular kept you awake?</td><td colspan="4">What would you say woke you up?</td><td>What do you feel affected your sleep?</td></tr>
<tr><td>I couldn’t get to sleep</td><td>My baby</td><td>Other</td><td>I had to go to the bathroom</td><td>My baby</td><td>Physical discomfort</td><td>I had a lot on my mind</td><td>Other</td></tr>
</table>

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Did it take you more than 30 minutes to get to sleep?		**Please share what happened with your baby that kept you up.**	**Please share what kept you awake.**		**Please share what happened with your baby that kept you up.**	**Please share what made you feel physically uncomfortable (i.e. too hot, too cold, pain, etc.)**	**Please share what was on your mind.**	**Please share what kept you awake.**	*[Collect open ended response]*
No	Yes				*[Collect open ended response]*				
	How come?			**Was there any other reason you may have been awoken?**					
	[Collect open ended response]			Yes *[Return to "**What would you say woke you up**?" above]*			No		
Did anything else affect your sleep?									
Yes				No					
What else affected your sleep? *[Return to **"What do you think affected your sleep?"** responses above]*									
On a scale of 1 to 4 (1 being Very Good and 4 being Very Bad), how would you rate your quality of sleep last night?									
[Collect open ended response]									
Thanks for sharing that. How did you feel when you woke up this morning?									
Tired		Well-rested		Other					
				How would you describe how you felt when you woke up this morning?					
				[Collect open ended response]					
Did you still feel tired in the afternoon?		**That's great! Did you feel tired in the afternoon?**		**Did you feel tired in the afternoon?**					
[All questions lead to these responses]									
Yes				No					

<table>
<tr><td colspan="5">Did you take a nap or manage being tired in any other way?</td><td rowspan="5">I’m glad to hear that! Would you like some additional information on improving sleep quality overall?</td></tr>
<tr><td rowspan="3">Nap</td><td rowspan="3">Caffeine</td><td>Medication</td><td rowspan="3">Other [Collect open ended response]</td><td rowspan="4">No</td></tr>
<tr><td>What medication did you take?</td></tr>
<tr><td>[Collect open ended response]</td></tr>
<tr><td colspan="3">Did this help?</td></tr>
<tr><td colspan="2">Yes</td><td colspan="2">No</td></tr>
<tr><td colspan="2">I’m glad to hear that you’re feeling less tired! Would you like some additional information on improving sleep quality overall?</td><td colspan="3">I’m sorry to hear that. Would you find it helpful if we shared some additional information on improving sleep quality overall?</td></tr>
<tr><td colspan="3">Yes</td><td colspan="3" rowspan="2">No</td></tr>
<tr><td colspan="3">Great! This link has a lot of information about improving sleep and sleep quality: http://www.healthhub.sg/live-healthy/510/sleep</td></tr>
<tr><td colspan="6">Thanks for chatting with me today!</td></tr>
</table>

Appendix III: Stress Script

<table>
<tr><td colspan="9">How did you sleep last night?</td></tr>
<tr><td colspan="5">Good</td><td colspan="4">Not well</td></tr>
<tr><td colspan="5"></td><td colspan="4"></td></tr>
<tr><td colspan="3"></td><td colspan="2"></td><td colspan="3"></td><td></td></tr>
<tr><td colspan="5">Thanks for sharing that. How many total hours of sleep did you get last night?
[Collect open ended numerical response and filter into below categories]</td><td colspan="4">Thanks for sharing that. How many total hours of sleep did you get last night?
[Collect open ended numerical response and filter into below categories]</td></tr>
<tr><td><7 hours</td><td colspan="2">≥7 hours</td><td colspan="2">I don’t know</td><td><7 hours</td><td colspan="2">≥7 hours</td><td>I don’t know</td></tr>
<tr><td rowspan="3">I’m glad you still feel well-rested. Did anything affect your sleep?</td><td colspan="2" rowspan="3">That is a good amount of sleep! Did anything bother you about your sleep?</td><td colspan="2">That’s ok, I only need an estimate.</td><td rowspan="3">What do you think affected your sleep?</td><td colspan="2" rowspan="3">That is a good amount of sleep. Why do you feel like you didn’t sleep well? Did anything bother you about your sleep?</td><td>That’s ok, I only need an estimate.</td></tr>
<tr><td colspan="2">[Collect open ended numerical response]</td><td>[Collect open ended numerical response]</td></tr>
<tr><td colspan="2">Please share what may have affected your sleep last night.</td><td>Please share what may have affected your sleep last night.</td></tr>
<tr><td colspan="9">[All questions lead to these responses]</td></tr>
<tr><td colspan="3" rowspan="2">I went to bed too late.</td><td colspan="2">I woke up during the night.</td><td colspan="2" rowspan="2">I woke up too early.</td><td rowspan="2">Other</td><td rowspan="3">Nothing affected my sleep.
[Skip to question below]</td></tr>
<tr><td colspan="2">Sorry to hear that, do you remember how often you woke up? [Collect open ended response]</td></tr>
<tr><td colspan="3">Sorry to hear that, what in particular kept you awake?</td><td colspan="4">What would you say woke you up?</td><td rowspan="2">What do you feel affected your sleep?</td></tr>
<tr><td>I couldn’t get to sleep</td><td>My baby</td><td>Other</td><td>I had to go to the bathroom</td><td>My baby</td><td>Physical discomfort</td><td>I had a lot on my mind</td><td>Other</td></tr>
</table>

<table>
<tr><td colspan="2" rowspan="2">Did it take you more than 30 minutes to get to sleep?</td><td rowspan="3">Please share what happened with your baby that kept you up.</td><td rowspan="3">Please share what kept you awake.</td><td rowspan="2"></td><td>Please share what happened with your baby that kept you up.</td><td>Please share what made you feel physically uncomfortable (i.e. too hot, too cold, pain, etc.)</td><td>Please share what was on your mind.</td><td>Please share what kept you awake.</td><td rowspan="2">[Collect open ended response]</td></tr>
<tr><td colspan="4">[Collect open ended response]</td></tr>
<tr><td rowspan="3">No</td><td>Yes</td><td colspan="8" rowspan="2">Was there any other reason you may have been awoken?</td></tr>
<tr><td>How come?</td></tr>
<tr><td colspan="2">[Collect open ended response]</td><td colspan="2">Yes
[Return to “What would you say woke you up?” above]</td><td colspan="5">No</td></tr>
<tr><td colspan="10">Did anything else affect your sleep?</td></tr>
<tr><td colspan="7">Yes</td><td colspan="3" rowspan="2">No</td></tr>
<tr><td colspan="7">What else affected your sleep? [Return to “What do you think affected your sleep?” responses above]</td></tr>
<tr><td colspan="10">On a scale of 1 to 4 (1 being Very Good and 4 being Very Bad), how would you rate your quality of sleep last night?</td></tr>
<tr><td colspan="10">[Collect open ended response]</td></tr>
<tr><td colspan="10">Thanks for sharing that. How did you feel when you woke up this morning?</td></tr>
<tr><td colspan="3" rowspan="2">Tired</td><td colspan="3" rowspan="2">Well-rested</td><td colspan="4">Other</td></tr>
<tr><td colspan="4">How would you describe how you felt when you woke up this morning?</td></tr>
<tr><td colspan="3">Did you still feel tired in the afternoon?</td><td colspan="3">That’s great! Did you feel tired in the afternoon?</td><td colspan="4">Did you feel tired in the afternoon?</td></tr>
<tr><td colspan="10">[All questions lead to these responses]</td></tr>
<tr><td colspan="8">Yes</td><td colspan="2">No</td></tr>
</table>

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<tr><td>What medication did you take?</td></tr>
<tr><td>[Collect open ended response]</td></tr>
<tr><td colspan="4">Did this help?</td></tr>
<tr><td colspan="2">Yes</td><td colspan="2">No</td></tr>
<tr><td colspan="2">I’m glad to hear that you’re feeling less tired! Would you like some additional information on improving sleep quality overall?</td><td colspan="3">I’m sorry to hear that. Would you find it helpful if we shared some additional information on improving sleep quality overall?</td></tr>
<tr><td colspan="3">Yes</td><td colspan="3" rowspan="2">No</td></tr>
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</table>

Appendix IV: Nutrition Script

<table>
<tr><td colspan="9">How did you sleep last night?</td></tr>
<tr><td colspan="4">Good</td><td colspan="5">Not well</td></tr>
<tr><td colspan="4"></td><td colspan="5"></td></tr>
<tr><td colspan="3"></td><td colspan="1"></td><td colspan="4"></td><td colspan="1"></td></tr>
<tr><td colspan="4">Thanks for sharing that. How many total hours of sleep did you get last night?
[Collect open ended numerical response and filter into below categories]</td><td colspan="5">Thanks for sharing that. How many total hours of sleep did you get last night?
[Collect open ended numerical response and filter into below categories]</td></tr>
<tr><td><7 hours</td><td colspan="2">≥7 hours</td><td>I don’t know</td><td><7 hours</td><td colspan="2">≥7 hours</td><td colspan="2">I don’t know</td></tr>
<tr><td rowspan="3">I’m glad you still feel well-rested. Did anything affect your sleep?</td><td colspan="2" rowspan="3">That is a good amount of sleep! Did anything bother you about your sleep?</td><td>That’s ok, I only need an estimate.</td><td rowspan="3">What do you think affected your sleep?</td><td colspan="2" rowspan="3">That is a good amount of sleep. Why do you feel like you didn’t sleep well? Did anything bother you about your sleep?</td><td colspan="2">That’s ok, I only need an estimate.</td></tr>
<tr><td>[Collect open ended numerical response]</td><td colspan="2">[Collect open ended numerical response]</td></tr>
<tr><td>Please share what may have affected your sleep last night.</td><td colspan="2">Please share what may have affected your sleep last night.</td></tr>
<tr><td colspan="9">[All questions lead to these responses]</td></tr>
<tr><td colspan="3" rowspan="2">I went to bed too late.</td><td>I woke up during the night.</td><td colspan="2" rowspan="2">I woke up too early.</td><td rowspan="2">Other</td><td rowspan="3">Nothing affected my sleep.
[Skip to question below]</td></tr>
<tr><td>Sorry to hear that, do you remember how often you woke up? [Collect open ended response]</td></tr>
<tr><td colspan="3">Sorry to hear that, what in particular kept you awake?</td><td colspan="4">What would you say woke you up?</td><td rowspan="2">What do you feel affected your sleep?</td></tr>
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<tr><td colspan="4">[Collect open ended response]</td></tr>
<tr><td rowspan="3">No</td><td>Yes</td><td rowspan="2">How come?</td><td colspan="7">Was there any other reason you may have been awoken?</td></tr>
<tr><td colspan="2">[Collect open ended response]</td><td colspan="3">Yes
[Return to “What would you say woke you up?” above]</td><td colspan="3">No</td></tr>
<tr><td colspan="9">Did anything else affect your sleep?</td></tr>
<tr><td colspan="6">Yes</td><td colspan="3" rowspan="2">No</td></tr>
<tr><td colspan="6">What else affected your sleep? [Return to “What do you think affected your sleep?” responses above]</td></tr>
<tr><td colspan="9">On a scale of 1 to 4 (1 being Very Good and 4 being Very Bad), how would you rate your quality of sleep last night?</td></tr>
<tr><td colspan="9">[Collect open ended response]</td></tr>
<tr><td colspan="9">Thanks for sharing that. How did you feel when you woke up this morning?</td></tr>
<tr><td colspan="3" rowspan="2">Tired</td><td colspan="3" rowspan="2">Well-rested</td><td colspan="3">Other</td></tr>
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<tr><td colspan="3">Did you still feel tired in the afternoon?</td><td colspan="3">That’s great! Did you feel tired in the afternoon?</td><td colspan="3">Did you feel tired in the afternoon?</td></tr>
<tr><td colspan="9">[All questions lead to these responses]</td></tr>
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SAP Danone Chatbot V1.0 11APR2019_FINAL

Final Audit Report 2019-04-11

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By:	Claire Fives (Claire.fives@obviohealth.com)
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"SAP Danone Chatbot V1.0 11APR2019_FINAL" History

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2019-04-11 - 4:27:30 AM GMT

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2019-04-11 - 4:59:47 AM GMT- IP address: 122.248.178.194

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2019-04-11 - 12:59:12 PM GMT