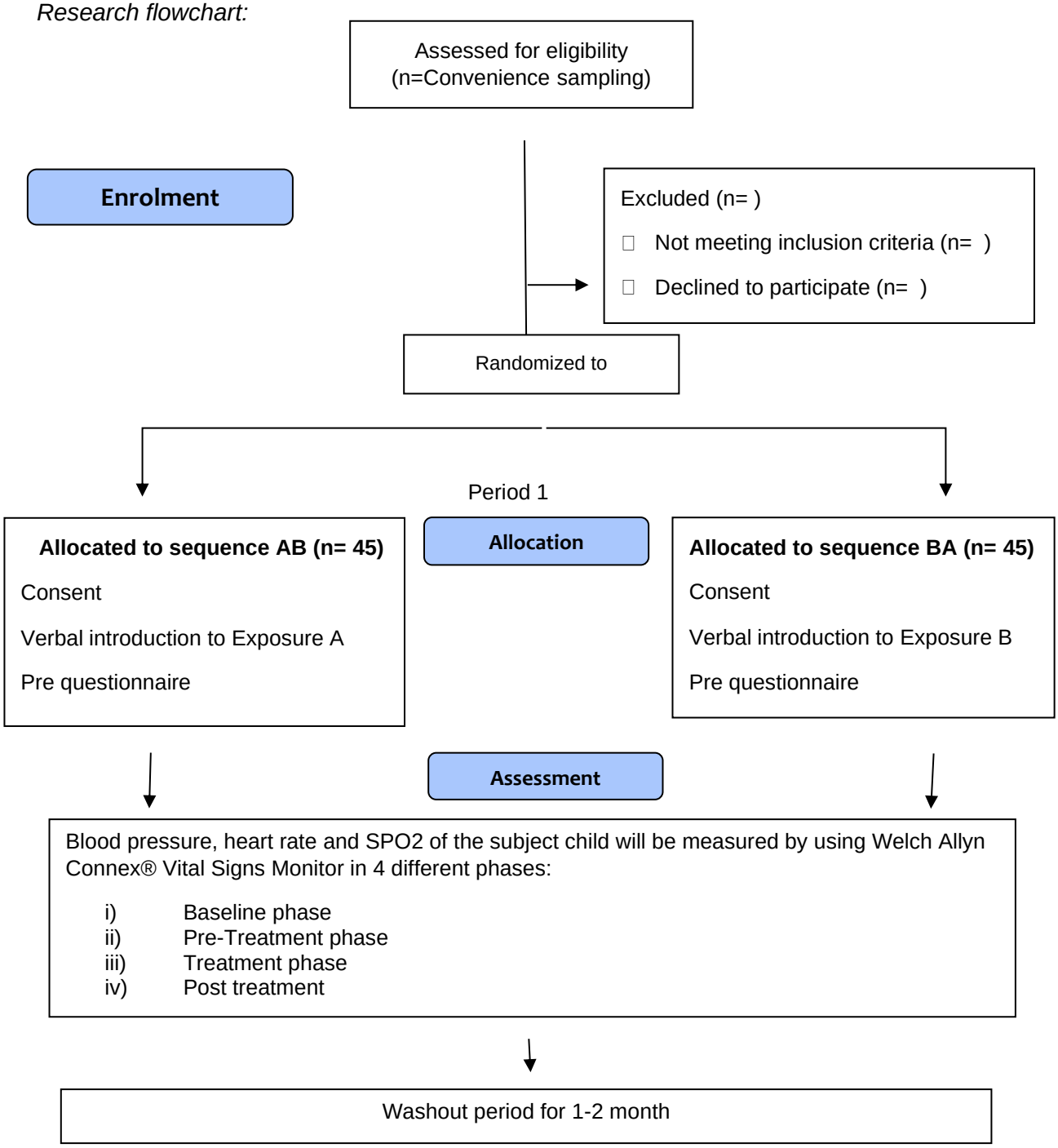
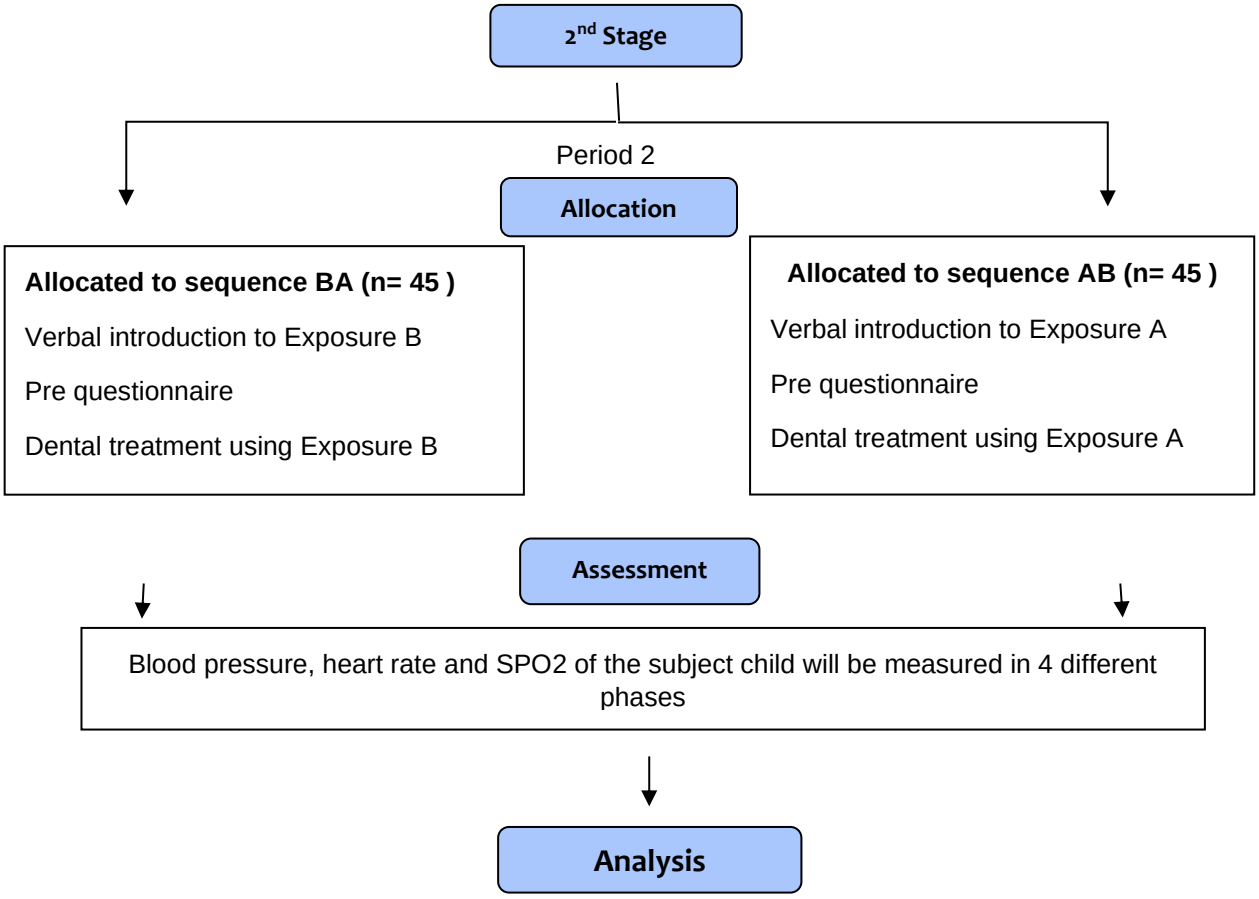
**Research flowchart Protocol:**

*Research flowchart:*






*Research design dan methodology:*

Research design : Randomized crossover trial , Longitudinal
Focus group : New patient / children with special needs and their caregivers attending Special Care Dentistry (Paediatric) and Paediatric Dentistry Clinic UiTM
Sampling : Convenient sampling method
Consent : Written consent

Research activities:
Subjects will received two treatments (exposures) sequentially over two periods and the order in which treatments received is randomised (known as the 2×2 or AB/BA design). Exposure A is basic BGTs while exposure B is passive immobilization with PB. Basic BGTs adopted in this study are; Tell-Show-Do (TSD), Distraction (D) or Positive Reinforcement (PR).

Block randomization will be applied to allocate sequencing group for the eligible subjects. Subject caregiver will select an envelope which are evenly divided into 2 types of sequencing groups which are 45 AB exposure sequence and 45 BA exposure sequence. The details regarding AB and BA exposures are explained in table below:

| Sequencing | 1st period | 2nd period |
|---|---|---|
| AB | Exposure A= Basic BGT(s) | Exposure B= Papoose Board |
| BA | Exposure B= Papoose Board | Exposure A= Basic BGT(s) |

Questionnaire : 16-items questionnaire
Translation of questionnaire: 1) Forward translation
Two forward translators are required to translate original

English-based questions into Bahasa Malaysia

2) Backward translation
Independent translator will translate the target language back to the source language

3) Harmonization and cognitive debriefing process results are reviewed by at least 2 specializes expertise

4) Face Validation by 10 targeted subjects
translation finalized

Treatment intentions: Dental prophylaxis or / and Class 1 restoration using slow speed handpiece.

Physiological changes measurement will be recorded by designated Dental Surgery Assistant (DSA): Subject child's blood pressure, heart rate and SPO2 will be measured by using Welch Allyn Connex® Vital Signs Monitor in 4 different phase which are as follows:

| Phase | Time of Measurement |
|---|---|
| Baseline | Subject child in the waiting room / surgery room sitting on chair |
| Pre- Treatment | Subject child lying down on the dental chair and proposed BGT (Exposure A) or wrap in PB (Exposure B) will be applied to subject child for 1-2 minutes. |
| Treatment | Chosen treatment either prophylaxis or caries removal (using slow speed handpiece; inside the oral cavity for 1-2 minutes. |
| Post Treatment | Subject child remains lying on the dental chair without Exposure A or Exposure B which lasted 1-2 minutes. |

After completion of the treatment, caregivers will be asked to complete a post intervention questionnaire using the same set of paper-based questionnaire.

Prior to the 2nd stage of the study, patient will be placed in washout period for 1-2 month to diminish impact of carryover effect. Subject child will repeat the same procedure as in 1st stage of the study for Exposure B. Exposure sequence will be vice-versa.

The questionnaire will undergo face validation with 10 parents (not included in the present study) to insure the clarity of the questions. Implementation of selected BMT and dental treatments on each children will be carried out by primary investigator (NSI), under the supervision of expert supervisors (IWM and SHH). Training on papoose board placement will be given by expert supervisor (IWM) prior to commencement of study.

**Statistical analysis:**

The data analysis will be done using the IBM SPSS software (Version 26.0, IBM Knowledge Center, USA).
Descriptive statistics will be performed to generate the mean, standard deviation, frequency, and percentage.
A value of $P < 0.05$ is considered statistically significant.

Intention-To-Treat (ITT) analysis will be used for every subject who was randomized according to randomized treatment assignment. ITT analysis Ignore noncompliance, protocol deviations, withdrawal, and anything that happens after randomization.

| Objective | Statistical analysis |
|---|---|
| 1 | Caregiver's acceptance, concern and consent will be analysed per questions. Comparison of paired scales median between Papoose Board and other basic BGTs will be analysed using Wilcoxon signed ranked test. |
| 2 | Caregiver's attitude toward the use of PB will be measured by calculating the total score of 6 additional Likert scale questionnaires. Comparison of mean attitude of PB usage pre and post intervention will be analysed using paired t-test. |
| 3 | Repeated measures Anova is used to compare 4 phase physiological means within groups. This analysis is to assess any significance difference of physiological changes on baseline phase, pre-treatment phase, treatment phase and post treatment phase in children with special need using PB and other basic BGTs during dental treatment. |
| 4 | Logistic regression will be used to assess the association of factors toward caregiver's acceptance, which was represented by question number. |