



Creating Aceptable Tablets 3D

Summary of the feasibility study to evaluate the mouthfeel of 3D printed tablets in children and young people.

Aim:

To evaluate the feasibility of a study investigating the mouthfeel of different sized 3D printed placebo solid dosage forms (SDFs) in children and young people (CYP) aged 4-12 years.



Method:

All participants in the CAT 3D Study had previously participated in the Creating Acceptable Tablets (CAT) Study, a feasibility study which assessed the swallowability and acceptability of different sized placebo tablets, and therefore only attempted to swallow one 3D printed tablet.

If the participant had successfully swallowed all three tablet sizes in the CAT Study (6mm, 8mm, 10mm) they were then randomised to receive any of the 3D printed tablets – 6mm, 8mm or 10mm diameter. If a participant had not successfully swallowed all tablet sizes, they were allocated a 3D printed tablet of equal size to the largest tablet they had successfully swallowed in the CAT Study. Following informed consent, participants were shown a short video demonstrating how to swallow a tablet. Participants were then provided with the sample 3D tablet and 150ml of still water in a cup. The volume of water required to swallow the tablet was measured, and further water was provided, where requested. The researcher observed and recorded the child's facial expressions as they swallowed the tablet, and an internal inspection of the mouth was conducted by the researcher to identify any residue or non-swallowed tablet. The participants assessed the swallowability, acceptability, mouthfeel and taste of the sample using a 5-point hedonic facial scale on a participant questionnaire. Faces 1-3 on the hedonic scale were deemed acceptable to the participant. The participants were also asked if the 3D printed tablet was a medicine, would they be willing to take it every day. In addition, they were asked which tablet felt better in the mouth as a comparison of mouthfeel between the GMP manufactured coated tablets (CAT study tablets) and the 3D printed tablets.

Results:

A total of 30 participants were recruited to the CAT 3D Study, 87% of whom successfully swallowed the 3D printed tablet that they attempted to take. Attributes of the 3D printed tablets were scored as acceptable by the following percentage of participants – swallowability (80%), mouthfeel/texture (87%), volume (80%), acceptability (83%) and taste (93%). 77% of children advised they would be happy to take the tablet every day if it were a medicine. Participants were also asked which tablets felt better in the mouth – the CAT

tablets or the 3D printed CAT 3D tablets, and the most popular response was that both felt ok (43%).

Conclusions:

The data from this study shows that 3D printed SDFs may be a suitable dosage form for children aged 4-12 years. The results from this feasibility study will be used to inform a larger, definitive study looking at the mouthfeel of 3D printed tablets in children.