

# Palatability and acceptability of multiparticulate formulations: adults vs. children comparison

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## Background knowledge



Evaluation of **palatability and patient acceptability** should be an integral part of the pharmaceutical development studies

Patient acceptability: “The overall **ability** and **willingness** of the patient and its caregiver to use the medicine as intended”



**Multiparticulate formulations** offer advantages over conventional solid and liquid dosage forms for paediatrics

However, little is known about palatability and patient acceptability of multiparticulate formulations

## Study aims



To develop methodology for palatability and acceptability testing

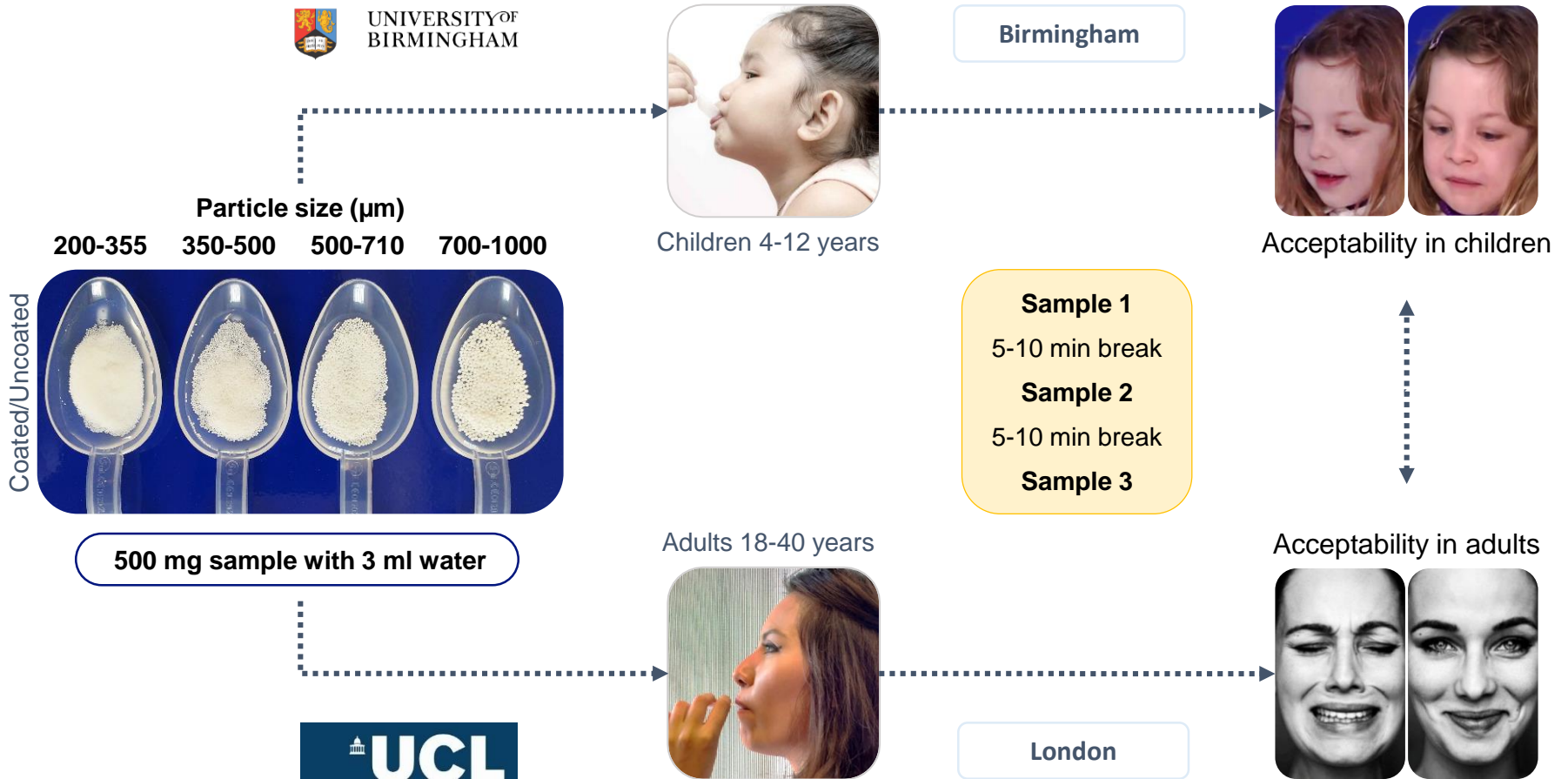
To generate knowledge towards a standardised methodology for assessment of palatability and patient acceptability



To evaluate multiparticulate formulations in adults and children

To assess the potential of multiparticulates for the administration of medicines to children

# Study design



# Outcome measures

## Researcher observations

(Before, during and after sample intake)



1 % volunteers able to swallow the complete dose of multiparticulates



2 Negative facial expressions and behaviours towards the samples

Facial expression	Negative behaviours
Eyes squeezed/shut	Voices resistance (prior)
Brow bulge (frown)	Voices disgust (post)
Nose wrinkle	Cries/screams
Pursed lips	Vomits

## Subject-reported outcomes

(Immediately after sample intake)

3 Hedonic scales: grittiness, volume, mouthfeel, taste



4 If this was a medicine, would you be willing to take this every day?



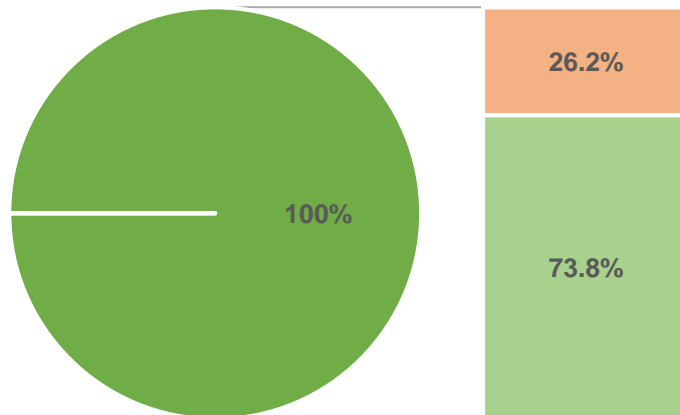
5 Text box for open-ended responses about samples

# Overall acceptability of multiparticulates

## Adults

61 participants (18-37 years; median = 22)

3 samples each → 183 administrations

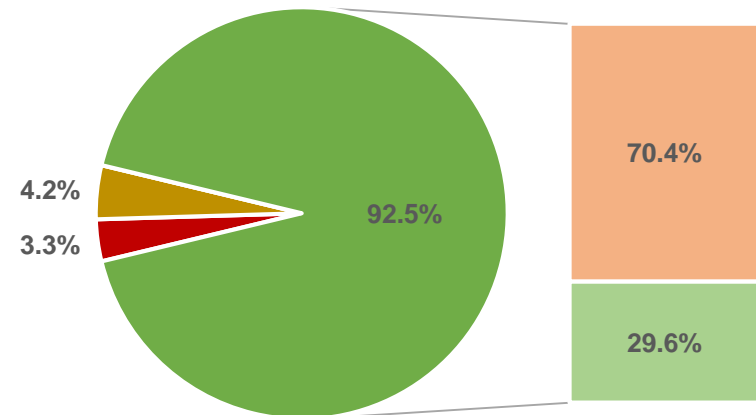


■ Refused 
 ■ Spat out 
 ■ Swallowed 
 ■ Not willing 
 ■ Willing to take sample everyday

## Children

71 participants (4-12 years; median = 7)

3 samples each → 213 administrations

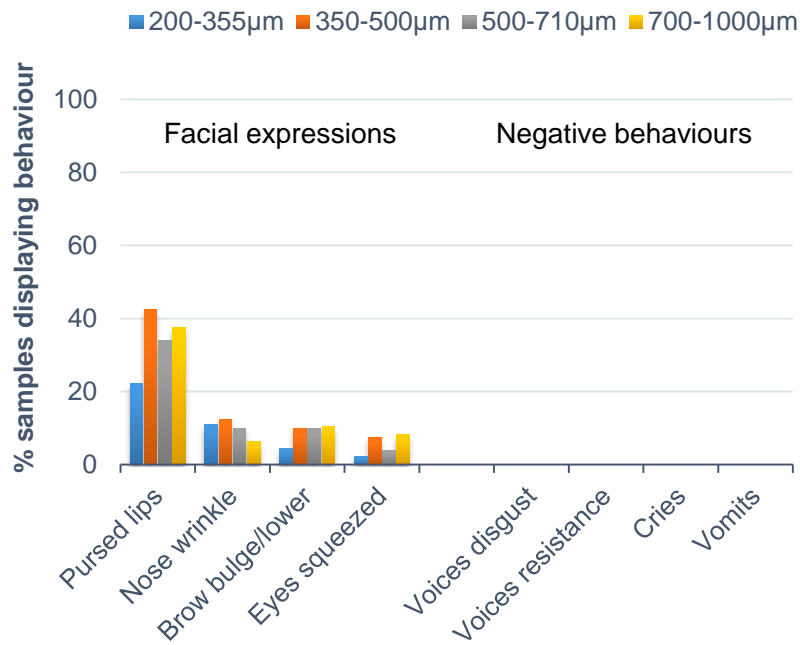


■ Refused 
 ■ Spat out 
 ■ Swallowed 
 ■ Not willing 
 ■ Willing to take sample everyday

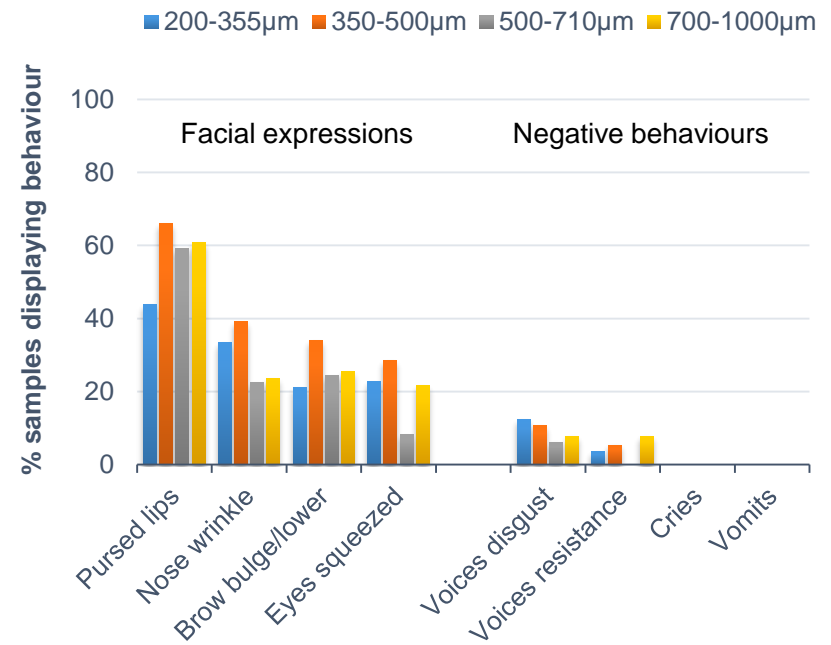
Wide acceptance of multiparticulates in both populations ?

# Researcher observations

## Adults



## Children



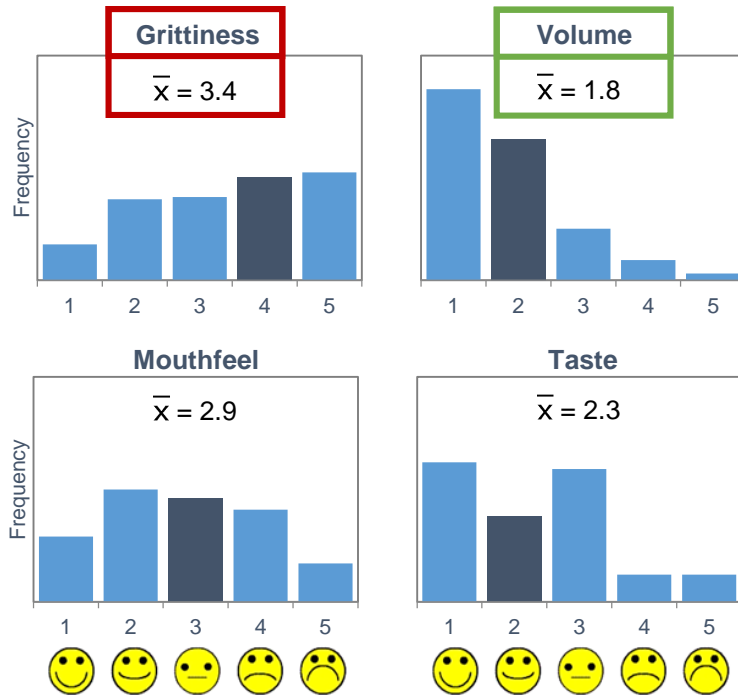
Facial expressions show some level of discomfort  
 No negative behaviours were observed in adults  
 No trend between observations and particle size



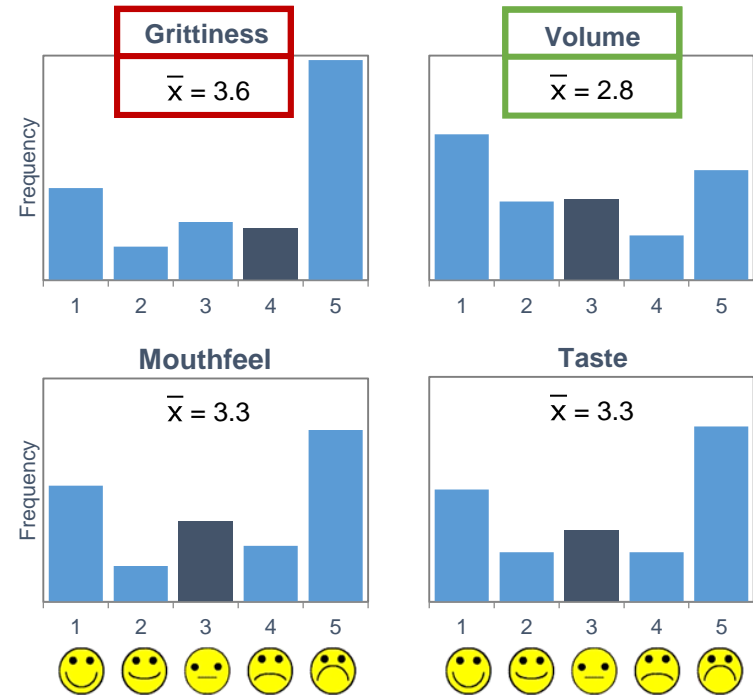
Consistently higher level of discomfort than adults  
 20 occasions voiced disgust, 9 voiced resistance  
 No trend between observations and particle size

# Subject-reported outcomes

## Adults



## Children

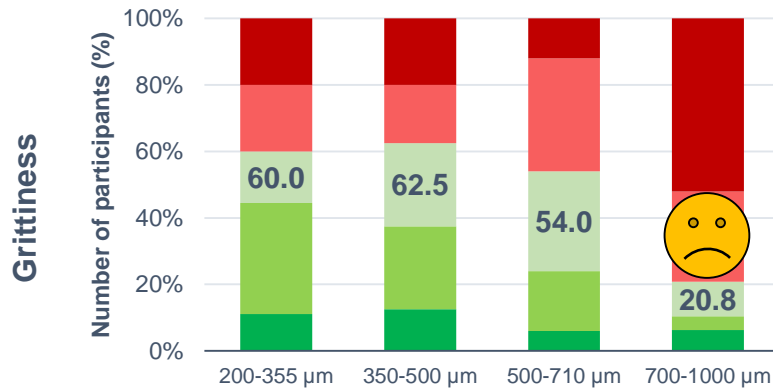


Samples were described as “tasteless” but the “gritty” feeling in the mouth was a limitation for palatability and acceptability. Samples were often described as “sandy”

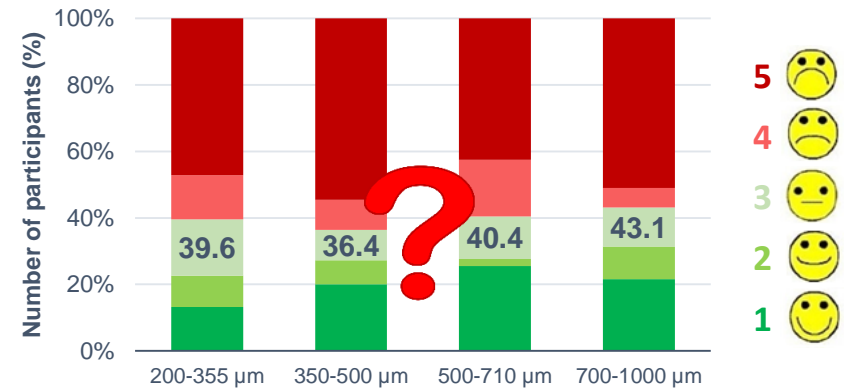


# Effect of formulation factors

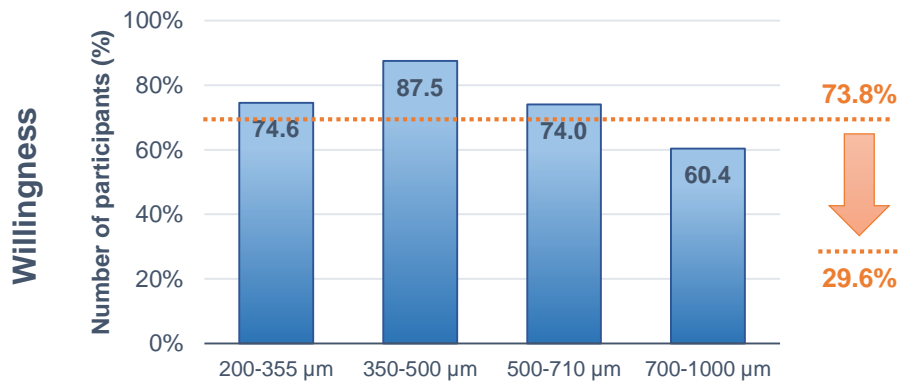
### Adults



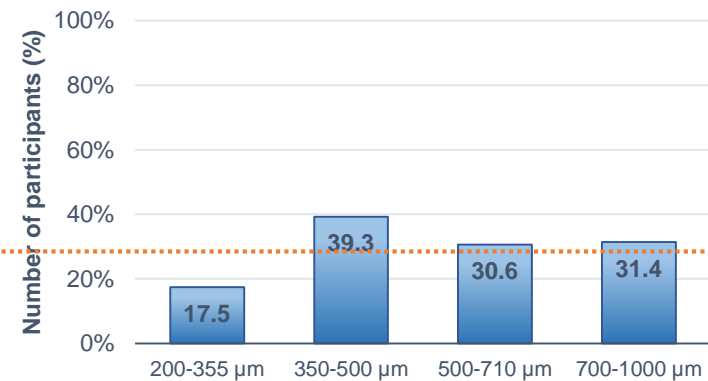
### Children



Preference for smaller sizes ( $p = 0.039$ )



No particle size preference ( $p = 0.306$ )



## Conclusions

Results of this study highlight methodology barriers to evaluate palatability and patient acceptability of pharmaceutical formulations



Further studies are needed to generate knowledge towards standardised methodology for palatability and acceptability testing

The **ability** to swallow the complete dose of multiparticulates (500 mg) was 92.5% in children and 100% in adults; however, the **willingness** to take the sample everyday was only 29.6% and 73.8%, respectively.

Textural aspects (i.e. grittiness) were the main barrier to palatability; In this regard adults preferred smaller particles (<700  $\mu\text{m}$ ) whereas children showed no size preference



## Acknowledgements:

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# Thank you for listening!