



## STUDY REPORT

# Asthma Breathing Record Study

A longitudinal, observational study to explore the Tidal Breathing Carbon Dioxide (TBCO<sub>2</sub>) waveform, measured using the N-Tidal C device, in asthma

TidalSense  
Cambridge, 2022  
[tidalsense.com](https://tidalsense.com)

**TidalSense**

## Our Team

- **Chief Investigator**  
Professor Anoop J Chauhan
- **Principal Investigator**  
Dr Thomas Brown- Consultant Respiratory Physician
- **Trial Coordinator**  
Dr Laura Wiffen - Wessex CRN Clinical Research Fellow
- **Deputy Director of NIHR Community Healthcare MedTech and IVD Cooperative**  
Professor Gail Hayward

## Sponsor

TidalSense

### Team

Dr Julian Carter  
Dr Ameera Patel  
John Foord  
Heather Harman  
Alla Kitov  
Henry Broomfield  
Henry Lim


### Funder

National Institute of Health Research (NIHR) Invention for Innovation Grant, number: II-LA-1117-20002.

## Investigators

- Dr Hannah Buckley – Consultant Paediatrician
- Professor Chris Butler – Professor of Primary Care and Clinical Director of the NIHR Community Healthcare, MedTech and IVD Cooperative
- Mr Milan Chauhan – Data co-ordinator
- Mrs Ruth DeVos – Specialist Respiratory Physiotherapist
- Ms Carole Fogg – Senior Lecturer, University of Portsmouth
- Dr Lauren Fox – Wessex CRN Clinical Research Fellow
- Dr Jessica Gates- Wessex CRN Clinical Research Fellow
- Mr Andrew Gribbin – Paediatric Research Nurse
- Dr Emily Heiden – Wessex CRN Clinical Research Fellow
- Dr Nikki Jarrett – Senior Lecturer, University of Portsmouth
- Dr Matthew Jones – Wessex CRN Clinical Research Fellow
- Dr Erika Kennington, Head of Research, Asthma UK
- Dr David Lodge – Wessex CRN Clinical Research Fellow
- Mrs Jayne Longstaff – Lead Respiratory Research Nurse
- Dr Ramon Luengo-Fernandez – Health Economist
- Ms Jennifer Marshall – Respiratory Clinical Research Associate
- Ms Madeline Rason – Respiratory Research Nurse
- Ms Heather Rutter – Senior Clinical Research Nurse
- Dr Hitasha Rupani – Consultant Respiratory Physician

# Why was the research needed



## Study aims and objectives

People with more severe asthma suffer from frequent asthma attacks that require regular hospital admissions. These attacks are difficult to predict and can devastate the lives of patients. We need a new tool that can help to predict when an asthma attack is going to happen. This would help people recognise an attack earlier and allow treatment to be started sooner. We studied a new breathing monitor, to see whether it can detect asthma attacks.

### **Why this study is important to people with asthma?**

Asthma attacks are usually diagnosed with a combination of people's reported symptoms (e.g. wheeze, cough, breathlessness) and some tests. Recognising an attack can involve a lot of breathing tests needing people to do forced manoeuvres that require a lot of effort. Some people can't perform these tests correctly, which makes it difficult for clinicians to come to a diagnosis. If asthma attacks could be accurately predicted by a simple, effortless breathing test then it would help both healthcare professionals and people living with asthma.

### **Study aim**

To determine characteristics within the TBCO<sub>2</sub> waveform shape, as measured by the N-Tidal C data collector device, that identify deteriorations in the user's respiratory condition, including changes leading to asthma exacerbations, and discriminate between poorly and well-controlled asthma.

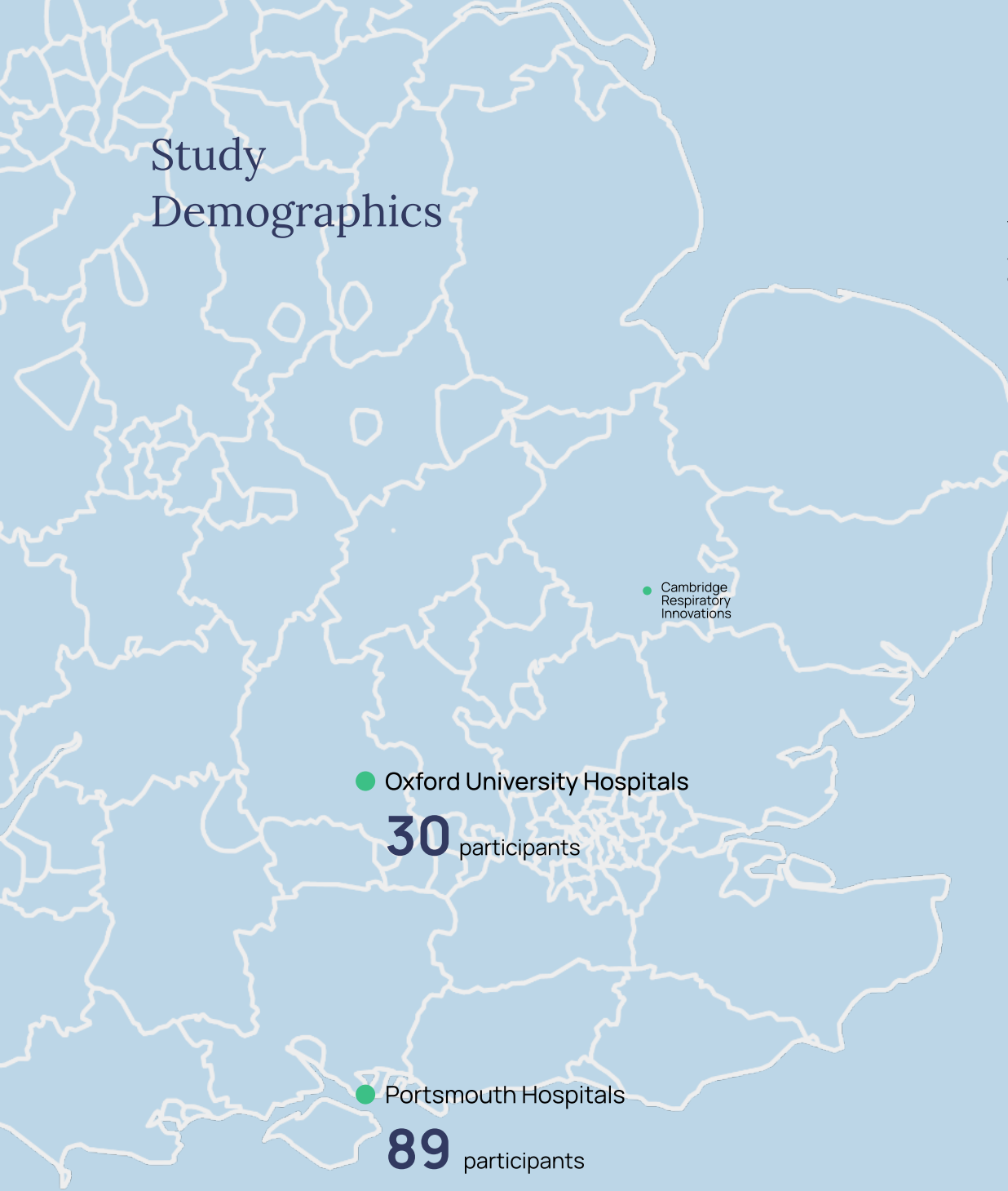
## Problem statement

Current methods of diagnosing and measuring disease control in asthma require forced expiratory manoeuvres that can be difficult to perform and equally difficult to interpret, especially during periods of poor asthma control. There is a need for a simple, effort independent method that can easily identify changes in respiratory function that will lead to asthma attacks accurately and benefit people with asthma by allowing timely treatment and preventing hospital admissions.

Expiratory capnography is a graphical measurement of CO<sub>2</sub> concentration during expiration. The characteristic shape of the Tidal Breathing CO<sub>2</sub> (TBCO<sub>2</sub>) waveform has been shown to change during asthma exacerbations, reflecting small airway obstruction, which returns to a normal pattern after treatment and recovery.

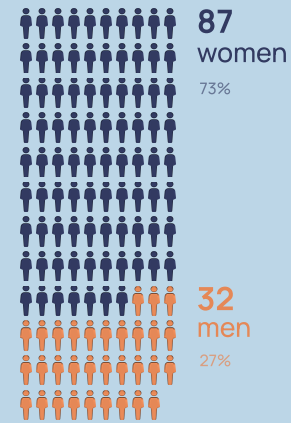
Currently, capnography is invasive, expensive and can only be recorded in specialist centres, via a nasal cannula and microstream sampling of expired carbon dioxide. The N-Tidal C, a new, hand-held device, has been developed to monitor the user's TBCO<sub>2</sub> waveforms whilst in the community, and detect changes that would reflect small airway obstruction. In previous studies, it has been shown that by analysing the breath features, the N-Tidal C was able to predict COPD exacerbations at least 48 hours in advance. This technology offers new possibilities of detecting airflow limitation in asthma, allowing early attack detection in an effort-independent manner.

# Study Demographics



## Participants

The recruitment for this research study took place in both primary and secondary care settings, although the majority of the data collection using the N-Tidal device took place in home environment. Participants with asthma were recruited from adult and paediatric outpatient clinics, community respiratory clinics, GP practices and emergency attendances and admissions to Hospital Trusts.



**119**  
number of participants that took part in the study



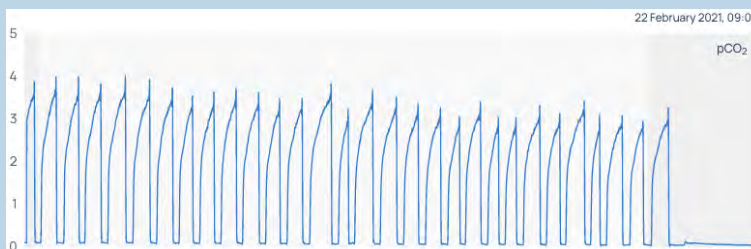
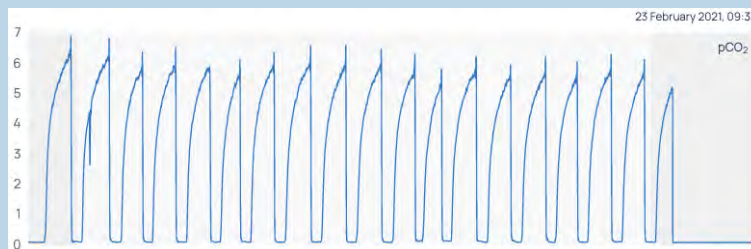
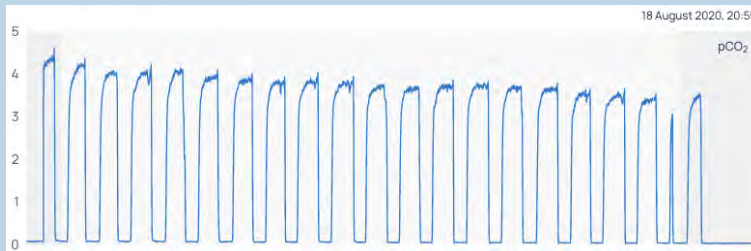
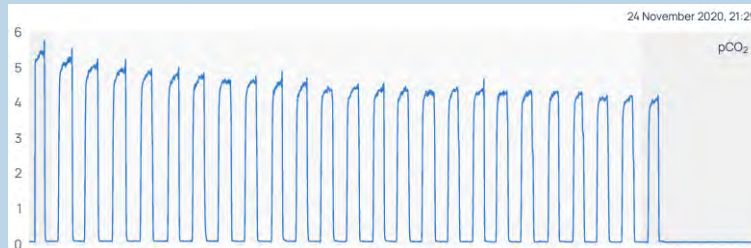
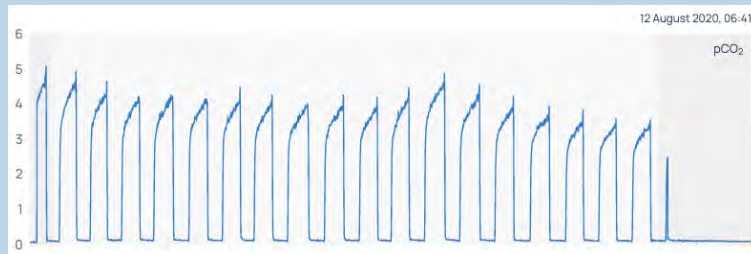
# Study design

The N-Tidal C, a new, hand-held device, has been developed to monitor the user's TBCO<sub>2</sub> waveforms whilst in the community and detect a change that would reflect small airway obstruction. This technology offers new possibilities of detecting airflow limitation in asthma, allowing early attack detection in an effort-independent manner.

The device was used in accordance with the N-Tidal C Instructions for Use. Participants were using the device twice daily before using their inhalers (morning and evening) and can use it up to 4 times a day if they feel they are having an exacerbation. The CO<sub>2</sub> concentration recordings were stored and analysed on the device and the data was automatically communicated to the secure database.

Participants held the device and breathed at their normal, relaxed rate of breathing through a mouthpiece for 75 seconds. They were asked to do this twice a day for 6 months (some participants spent up to 12 months). The device was not intended to be used in crowded rooms, near a vehicle exhaust, near open flames, near cigarettes, immediately after drinking a hot beverage or a fizzy drink, or where there is a strong breeze. These conditions may interfere with the data capture of the device.





## Monitoring

The participant's use of the N-Tidal C data collector device was monitored remotely throughout the study and also assessed at each visit. The study team checked that the participant is using the device correctly and provided additional training if needed. The usage of the N-Tidal C was reviewed with the participant, and the study team confirmed that the mouthpieces and breath pathway had been appropriately replaced at the required time intervals.

The study team used the Research Dashboard (below) to monitor breath records (left) and parameters such as Adherence and Breath Quality (you will read more about these in the coming sections). The Dashboard Expiratory capnography is a graphical measurement of CO<sub>2</sub> partial pressure during expiration. The characteristic shape of the Tidal Breathing CO<sub>2</sub> (TBCO<sub>2</sub>) waveform has been shown to change during asthma exacerbations, reflecting small airway obstruction, which then returns to a normal pattern after treatment and recovery. Currently, capnography is invasive, expensive and can only be recorded in specialist centres, via a nasal cannula and microstream sampling of expired carbon dioxide.



# Days on a study

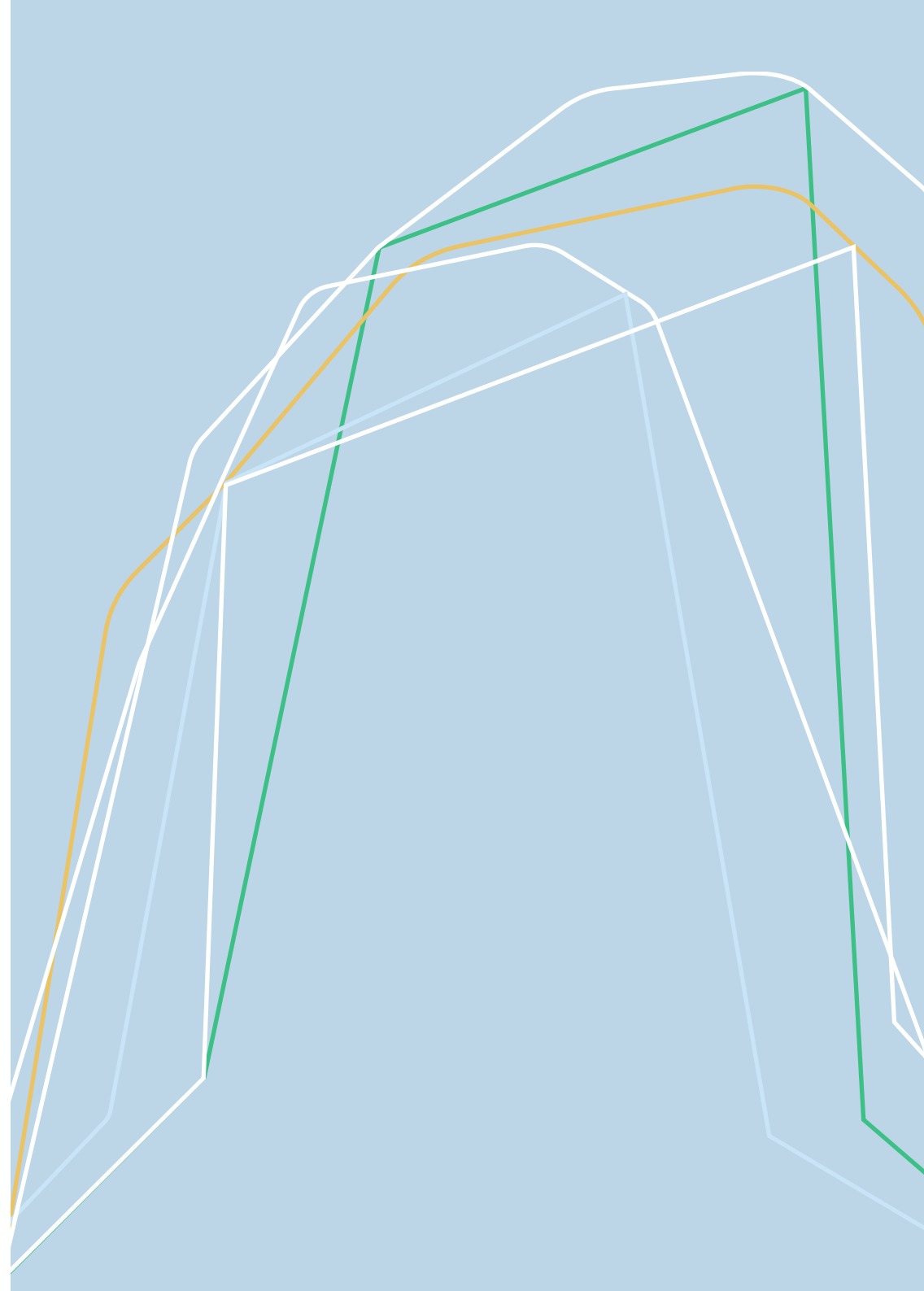
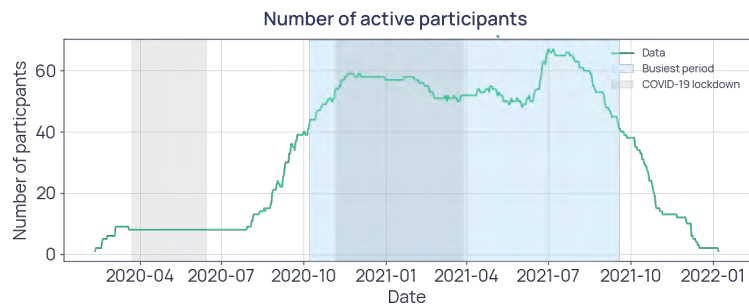
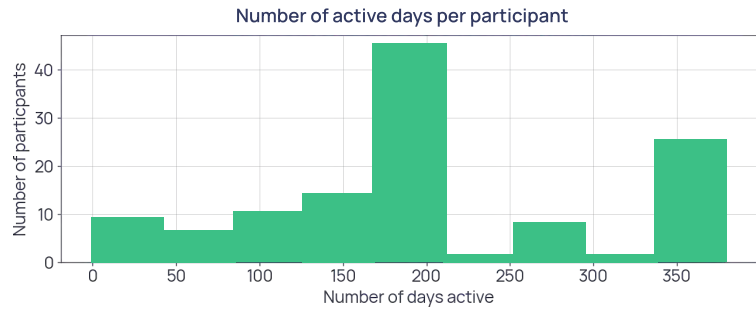
Participants were asked to spend 6 months on a study and used the N-Tidal device twice a day, everyday. On average participants were on the study for 201 days. The longest period a participant spent on the study was 379 days (more than a year). 62 participants (52%) voluntarily stayed on the study for more than 6 months.

## 201

average number of days a participant was on the study

## 379

maximum number of days a participant was on the study





# Capnography metrics

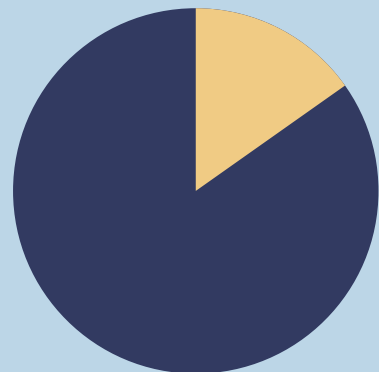
# 38026

breath records

were collected on this study between 11 February 2020 and 7 January 2022

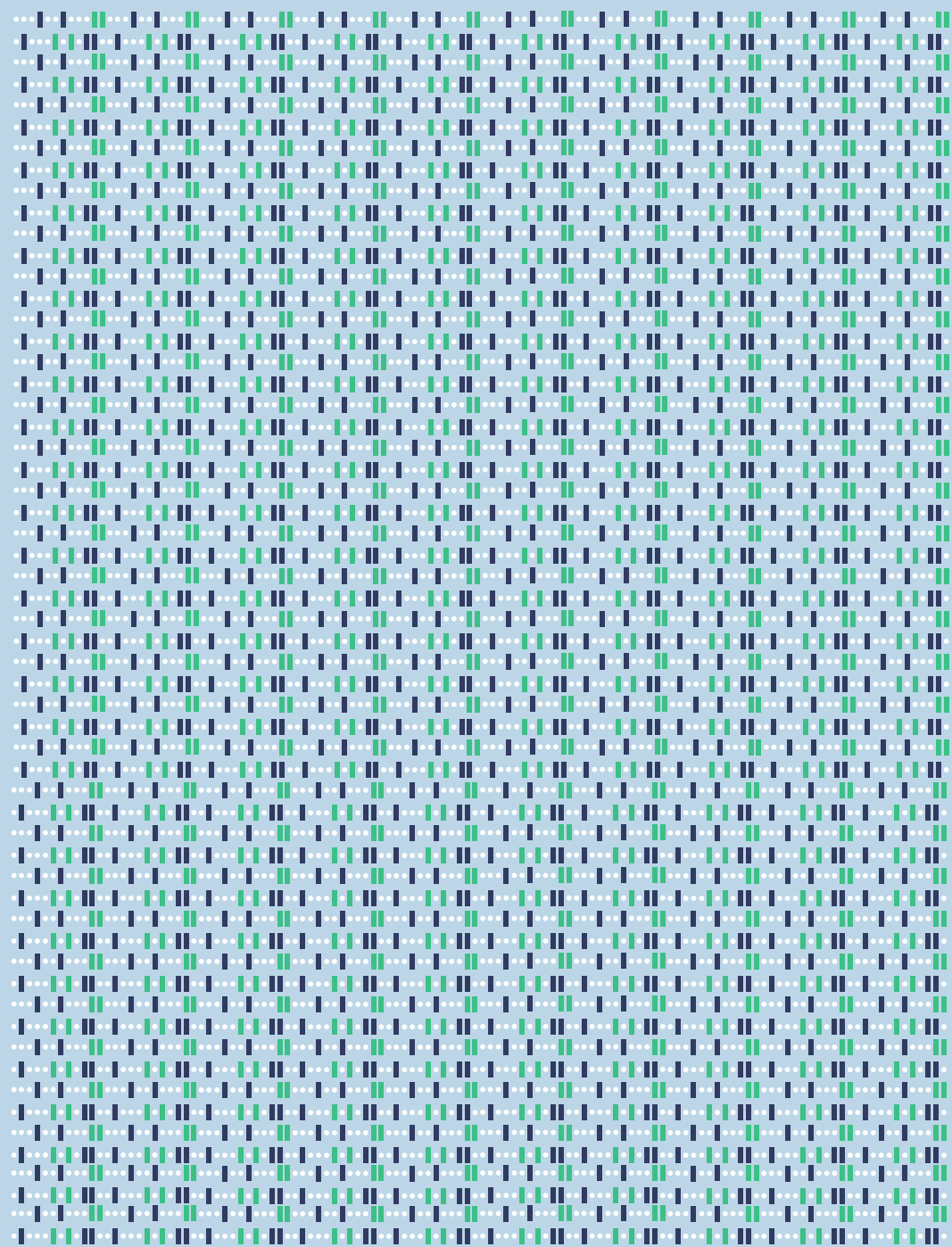
# 859898

number of identified individual breaths taken



4777 (12.6%)  
breath records were not  
used for data analysis

33249 (87.4%)  
breath records were used  
for data analysis



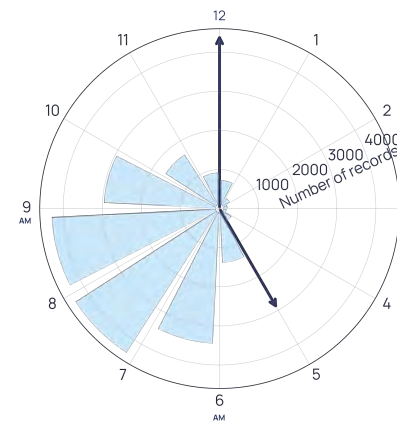
# Adherence

Adherence is a cumulative measure of how consistently participants were using the handset over the study period. Participants were asked to use the N-Tidal device twice a day every day. A score of 1 (100%) means that a participant were using it twice a day every day for the whole duration of a study. A score of 0.8 (80%) means that it was used twice a day in 80% of the days on a study. Mean adherence score for all participants on a study is 72% which shows a good adherence to using a device. The highest adherence score of a participant on the study was 99%. Some reason that resulted in lower adherence scores were identified and include: hospitalisation and worsening of exacerbations and other respiratory symptoms.

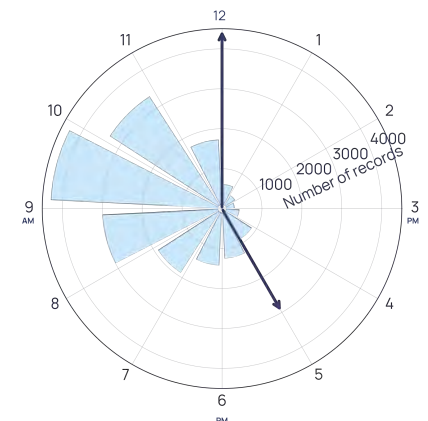
Mean Adherence Score Per Participant



Recording times AM



Recording times PM



# Breath Quality

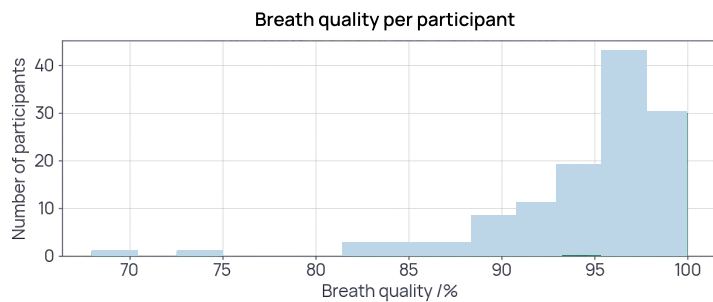
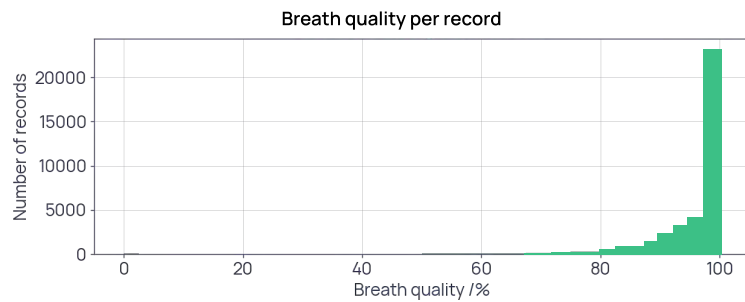
The Breath Quality measure indicates the percentage breaths captured that were good quality during the latest breath record (i.e. the participant was not nose breathing, not swallowing, not coughing, used only indoors, etc.). This measure helped study coordinators to observe how well participant are using the handset and whether they require retraining on how to deliver breath records.

# 95.5

mean breath quality  
per record

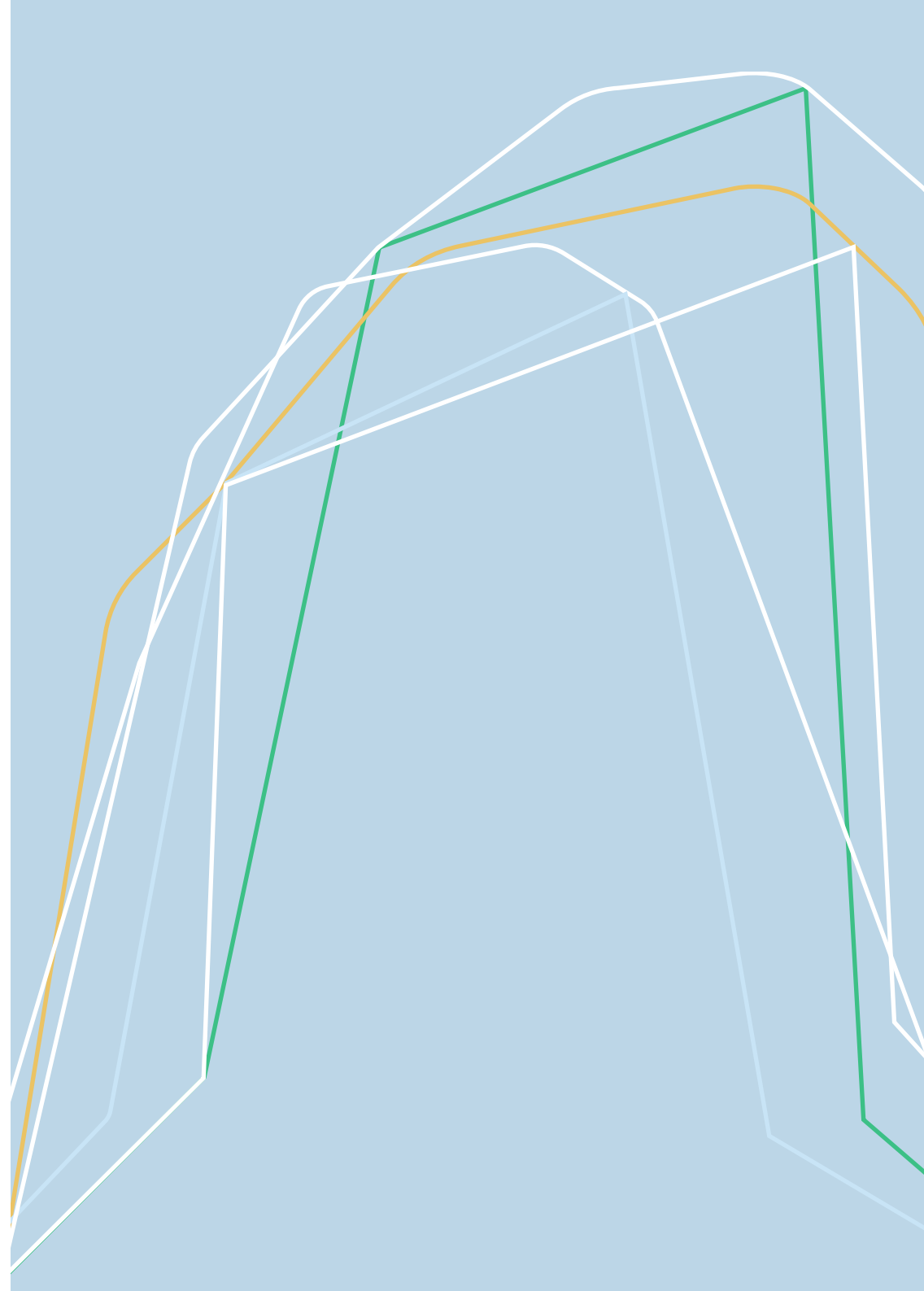
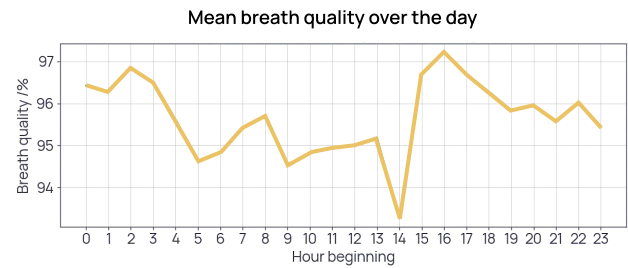
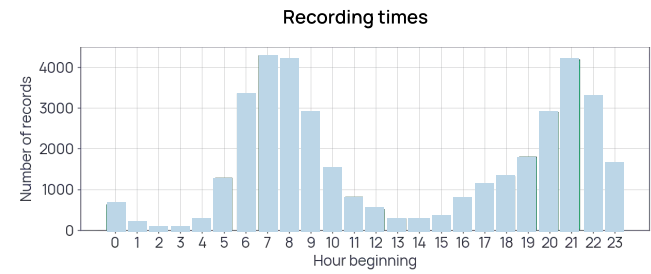
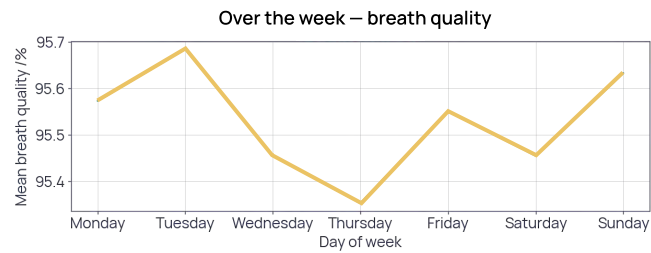
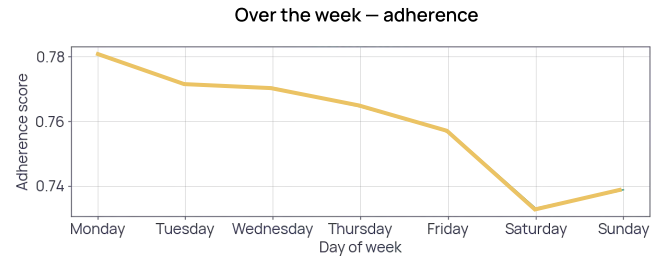
# 94.9

mean breath quality  
per participant



# Metrics over time

The trends in adherence over time do give statistically significant differences, however there is no statistical significance in breath quality variations during the day or the week.



# Exacerbations

## General statistics

There are 5.4 million people in the UK who suffer from asthma and 334 million people globally. 500,000 of these patients in the UK experience severe disease with frequent exacerbations.

## ABRS exacerbations

Exacerbations on ABRS were identified either through The Message Dynamics system or the participant contacting the research teams directly. Participants were reported the exacerbation status twice a week on Mondays and Thursdays.

**651**

number of Message Dynamics exacerbation triggers

**28**

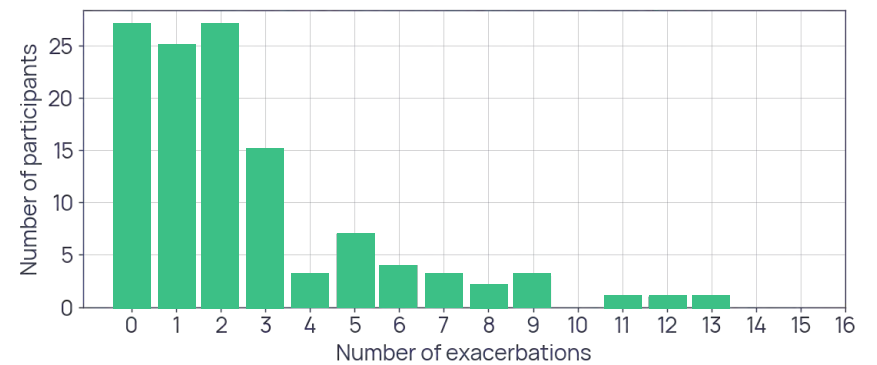
number of telephone exacerbation reports

**532**

number of confirmed asthma exacerbation reports

Number of confirmed different ( $\geq 14$  days apart) asthma exacerbation reports: 295  
Mean number of confirmed different ( $\geq 14$  days apart) asthma exacerbation reports per participant: 2.5  
Minimum number of confirmed different ( $\geq 14$  days apart) asthma exacerbation reports per participant: 0  
Maximum number of confirmed different ( $\geq 14$  days apart) asthma exacerbation reports per participant: 13

Number of exacerbations per participant





## Further results

The information gained from ABRS has been invaluable to our future endeavours. It has significantly contributed to our understanding about how our handset is used, and how we can enhance its features to improve its accessibility and accuracy.

Specifically, exacerbation data has been pivotal to our research. Not only are we making progress to generate more complex models that will forecast asthmatic exacerbations, we have also seen that different people vary in their presentation of TBCO<sub>2</sub> waveform characteristics. Using this capnography information, a measure of small airway obstruction was developed, whose variability over time has contributed to identification and grouping of patients. This could help to develop personalised patient treatments in the future and will inform our research directions moving forward. This study's contributions will culminate in an optimised product to aid healthcare institutions care for asthmatic patients more efficiently, and most importantly, improve the quality of life of those living with asthma.