Home Spirometry as an Endpoint in Interstitial Lung Disease
Clinical Trials – Lessons Learned
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Why is measuring lung function important in interstitial lung disease?
- Many types of interstitial lung disease (ILD) cause scarring in the lungs – also known as pulmonary fibrosis. Scarring builds up in the lungs over time and means that the lungs do not work as well as they used to.
- Measuring lung function can help people with ILD and their doctors understand if their disease is getting worse and can help measure if a treatment is working.
- When new medicines to treat ILD are tested in clinical studies, researchers also measure people’s lung function to see if the new medicine has an effect.

What is home monitoring of lung function?
Home monitoring of lung function is when people measure their lung function at home with a portable device – known as a spirometer. A spirometer measures how much air a person can breathe in and out after taking a big breath as possible – known as forced vital capacity.

Benefits of home spirometry
- People do not have to travel to a clinic to have their lung function measured.
- Some types of spirometer let people see their own results. This can give people a greater understanding of the disease and help them to discuss their treatment options with their doctor.
- People in the uILD study received a medicine to treat a different type of ILD (IPF – a type of ILD) and found it helped them.
- People in STARMAP and STARLINER received pharmaceuticals to treat their disease.
- People in STARLINER received a placebo as part of the study and found that 11% were discouraged when their results were too low.

How to perform home spirometry
1. Sit comfortably and practice breathing in deeply and breathing out gently a few times.
2. Breathe in again as deep as possible, this time quite fast.
3. Form a seal with your lips around the mouthpiece of the spirometer.
4. Breathe out as fast and hard as you can until your lungs are empty.

What do we know about the people who took part in these studies?

<table>
<thead>
<tr>
<th>uILD study</th>
<th>STARMAP study</th>
<th>STARLINER study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of people who took part</td>
<td>253</td>
<td>60</td>
</tr>
<tr>
<td>Number of people who received pirfenidone</td>
<td>59 years</td>
<td>69 years</td>
</tr>
<tr>
<td>Number of people who received placebo</td>
<td>70 years</td>
<td>69 years</td>
</tr>
<tr>
<td>Number of people with IPF</td>
<td>69 years</td>
<td>64 years</td>
</tr>
<tr>
<td>Number of people with unclassifiable ILD (uILD)</td>
<td>69 years</td>
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</tbody>
</table>

What was the average age of the people who took part?

| 70 years | 59 years | 64 years |

What were the key challenges associated with home spirometry?

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<th>uILD study</th>
<th>STARMAP study</th>
<th>STARLINER study</th>
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<tbody>
<tr>
<td>Were people's lung function results immediately transferred to their doctor electronically?</td>
<td>☑</td>
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<tr>
<td>Could the people taking part in the study see their own lung function results?</td>
<td>☑</td>
<td>☑</td>
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<tr>
<td>Were people's lung function results immediately transferred to their doctor electronically?</td>
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What were the key challenges associated with home spirometry?

- Some people showed a lot of variation in their home measurements of forced vital capacity.
- When the changes in forced vital capacity over time were compared between measurements taken at home and in hospital, some patients showed different patterns of change.
- Some people had trouble understanding how to use the spirometer.
- There were connectivity/data transfer problems between the spirometers and the digital platforms used to collect results in these studies.

What did people in the studies manage to perform home spirometry?

- 88% of blows in the STARMAP study were ‘good’
- 54% of blows in the STARLINER study were ‘good’

REFERENCES

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