

Please note that this summary only contains information from the full scientific article:

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How user feedback helped guide the design of the SmartClic®/ClicWise® injection device



Auto-injector

<AW-toh-in-JEK-ter>

Chronic

<KRAH-nik>

Date of summary: January 2023

Program start date: July 2018

Program end date: November 2019

The full title of this article: Design development of the SMARTCLIC®/CLICWISE® injection device for self-administered subcutaneous therapies: findings from usability and human factor studies

Key takeaways

- Chronic diseases are health problems that last for a long time or sometimes lifelong.
- In these studies, researchers worked with people with chronic diseases, caregivers, health care experts, and specialists to design the SmartClic®/ClicWise® auto-injection device.
- Researchers found that the final design of the device was easy to use, safe, and effective.

The purpose of this plain language summary is to help you to understand the findings from recent research.

- This summary reports the results of 7 studies. Health care experts should make their decision on the most appropriate injection device together with a patient based on individual patient needs.

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FEATURE



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What did these studies look at?

- Researchers carried out a number of studies to help design a new auto-injection device for people with chronic diseases.

What are chronic diseases?

- A chronic disease is a long-lasting health problem. It is not life threatening at first but will often get worse over time. It can be controlled with treatment but cannot be cured.

How are chronic diseases treated?

- Some people with chronic diseases take medicines that need to be injected under the skin (subcutaneous) using a syringe.
- Injecting medication themselves at home can have many benefits because people:
 - are more likely to take their medicine regularly;
 - can feel more in charge of their disease and their treatment;
 - do not have to rely on caregivers to take their medicine; and
 - may experience less stress of living with a chronic disease and improve their day-to-day life.
- Some people with chronic diseases may have pain or limited movement in their hands. This means they may find it difficult to inject themselves with their medication.
- Some people who inject their own medicines dread their injections and have to mentally prepare themselves. As a result, people might delay or skip taking their medicines.
- Injection devices called **auto-injectors** have been developed to help people who self-inject their medicines.
 - Auto-injectors are easy to use and can help people take their medicines regularly. This helps people to manage their disease more effectively.

How does the SmartClic/ClicWise auto-injector work?

- SmartClic/ClicWise is a new type of auto-injector device that can be used again and again. It is held in the hand and is loaded with containers (cartridges) filled with medicine. These containers can be thrown away after use.

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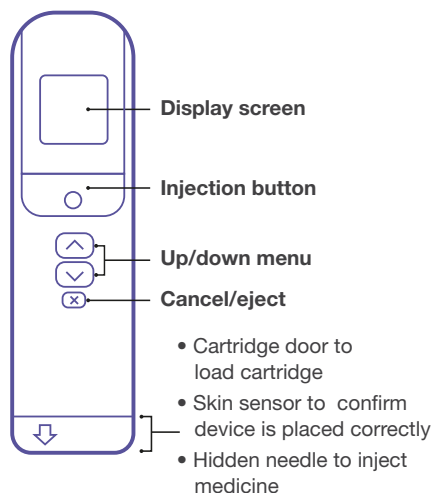


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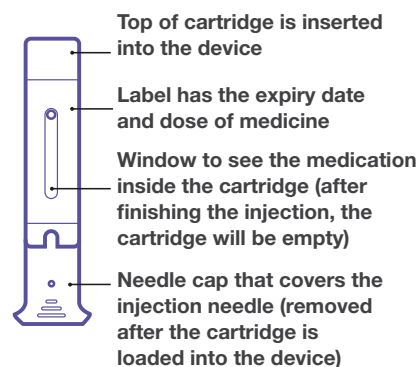
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What do the SmartClic/ClicWise device and medicine cartridge look like?

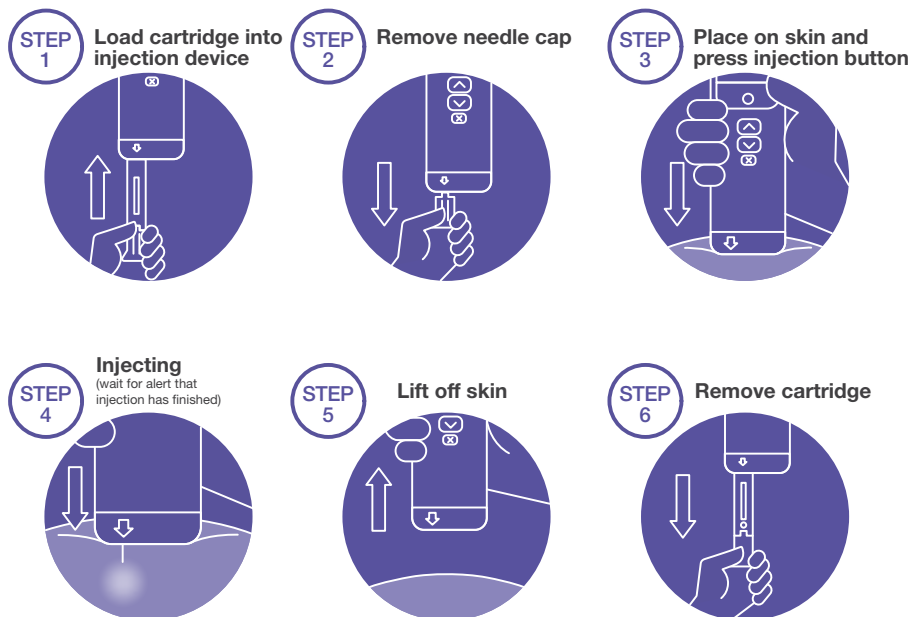
SmartClic/ClicWise device



Medicine cartridge



How does the SmartClic/ClicWise device work?



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- SmartClic/ClicWise is approved for use in Europe, Japan, Colombia, and Argentina at this time. It is also being considered for use in many other countries around the world.
- Researchers are also developing a mobile app for the SmartClic/ClicWise device to use on smartphones and tablets.
 - This optional mobile app will allow people to privately:
 - track the dates and times they inject their medicine;
 - record changes in their symptoms on their mobile device; and
 - choose to share their information with their doctor.



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What was the aim of these studies?

- This summary describes 7 studies that researchers carried out to develop the SmartClic/ClicWise auto-injection device.

2 User preference studies

- Researchers carry out user-preference studies to find out what type of device people would prefer to use.
 - In a user preference study, people test different versions of the device.
 - They give their opinions, either in person or online, on which version they prefer and how to improve the device.

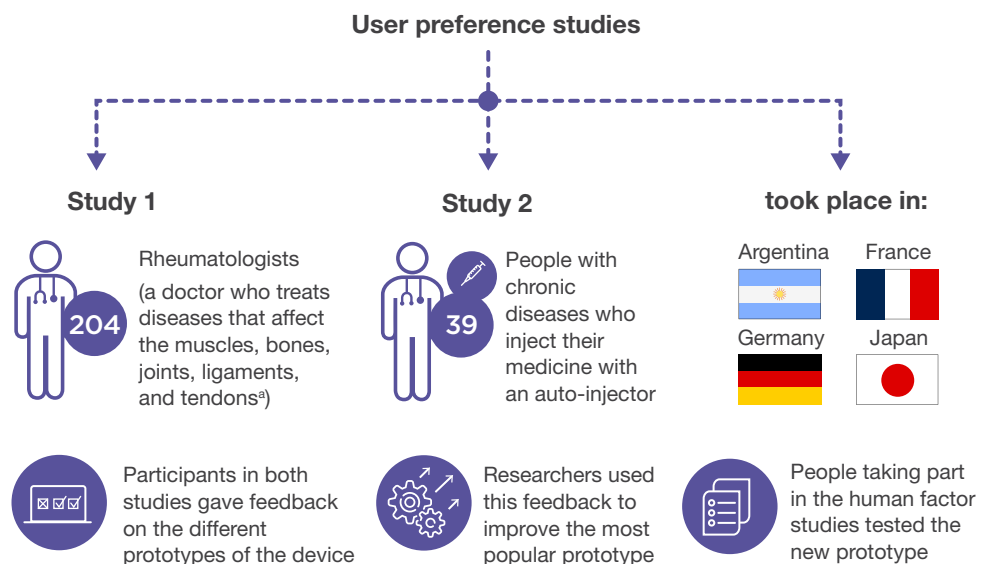
4 Human factor studies

- Researchers then carry out human factor studies to see how people use different prototypes of the device.
 - A prototype is an early version of a device that is created to test a design.
 - In a human factor study, people test how safe and easy the device is to use. They also give feedback on how to improve the device.
- Researchers used information from these 6 studies to improve the design and make the device user-friendly.

1 Injury prevention study

- Researchers also carry out injury prevention studies to test the safety of the device.
 - Licensed health care experts test how safe the device is to use.

Who took part in these studies?



* **Joint** - where 2 or more bones come together, like your shoulder or ankle. **Ligament** - a strong band of tissue that holds your joints together. **Tendon** - a strong band of tissue that attaches muscle to bone.

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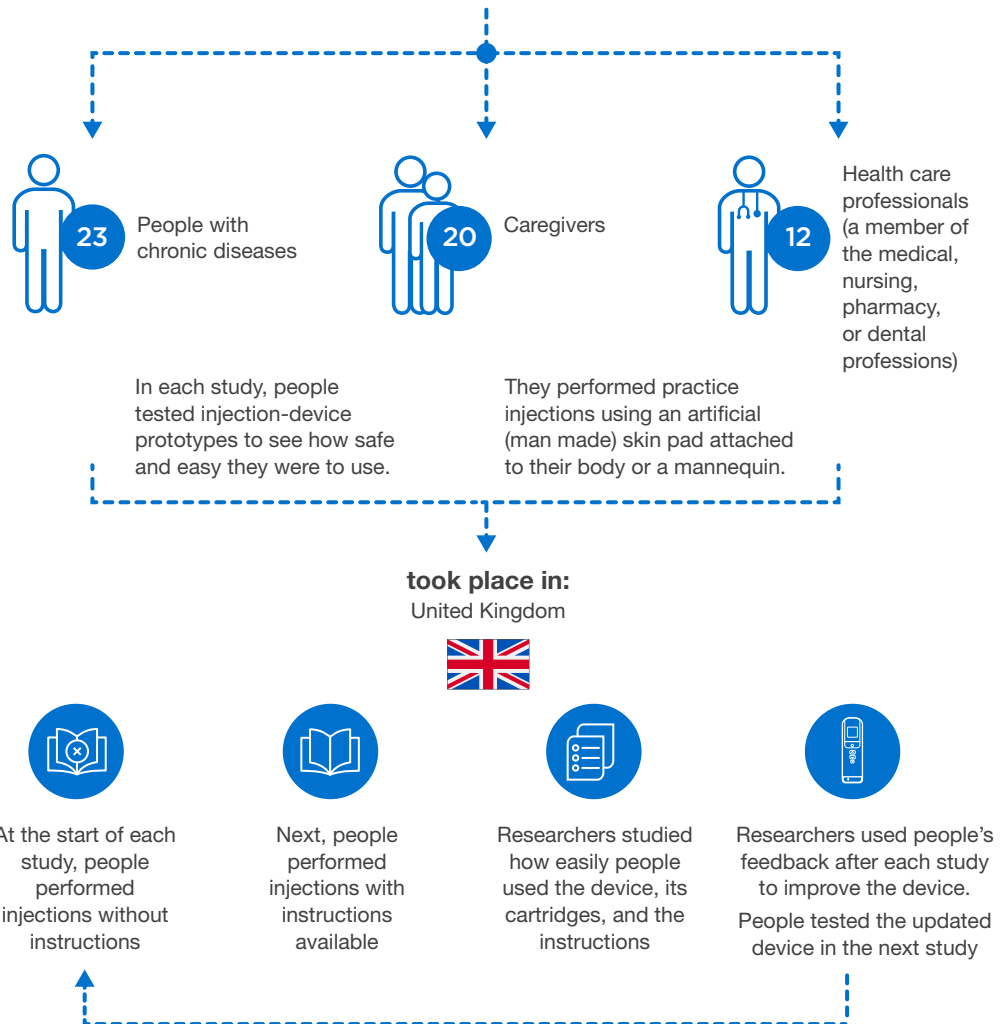
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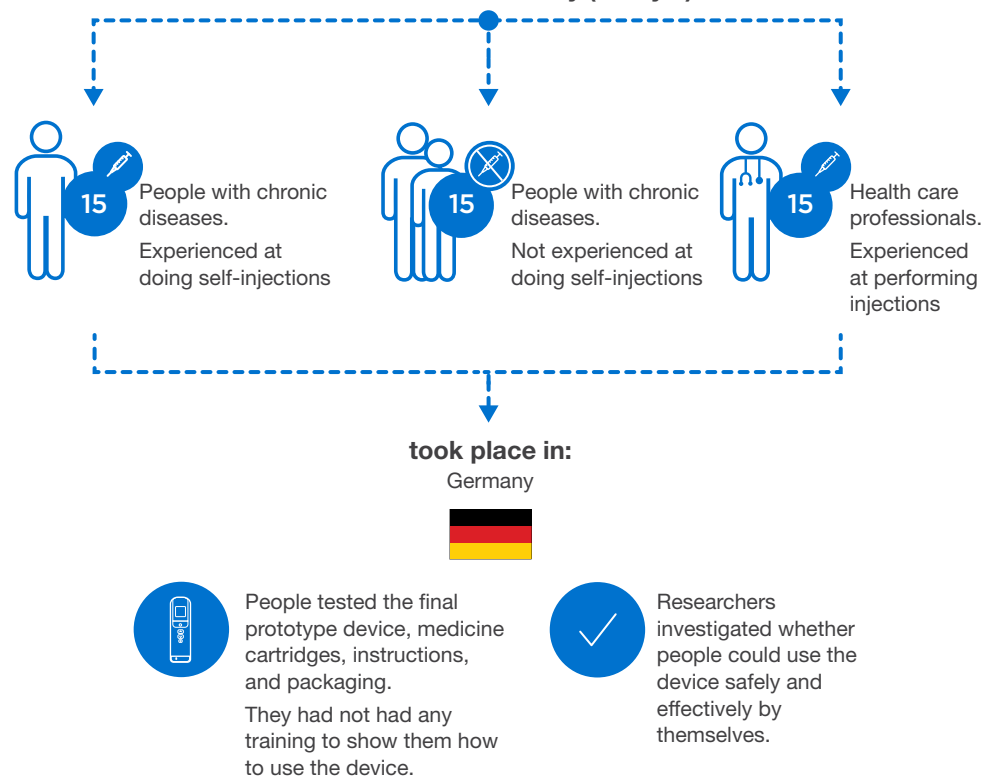
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Human factor studies (Studies 1, 2, and 3)



Final human factor study (Study 4)





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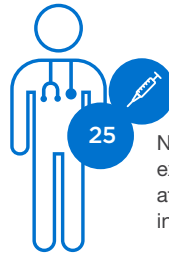
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Sharps injury prevention study - nurses



25 Nurses experienced at performing injections

took place in:
Germany



The device has safety features to protect people from accidentally hurting themselves with the needle.
Nurses were trained how to safely use the final device prototype. They each performed 20 practice injections using an artificial skin pad.



Researchers studied if the nurses could get hurt with the needle when performing injections

What were the results of the studies?

User preference studies

- People who took part in the user preference studies gave feedback on the different prototypes.

User Preference Study 1 — Feedback from rheumatologists

Benefits of the device



People would be more likely to keep taking their medicine regularly because of:



injection reminders



the ability to track their previous injections



improved experience with self-injection using the device



Bluetooth connectivity and a mobile app to record, plan, and remind people about their injections



may help some people feel more in charge

Weaknesses of the device



People who are older or disabled may not find the device straightforward to use



People using the device may require training



Display battery level or number of injections remaining should be added to the device.
Make the device re-chargeable



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User Preference Study 2— Feedback from people with chronic diseases

Suggested improvements for the device



Make sure people's personal information is secure to maintain patient-doctor trust



Confirm correct positioning of the device on skin and successful self-injection



Make the device smaller and lighter



Make surface of the device easier to hold

People chose this prototype because of key features that improved handling and use:



Smaller overall size made it easier to hold



Positioning of a large start and injection button below the display screen made the device easier to see the screen when using the device

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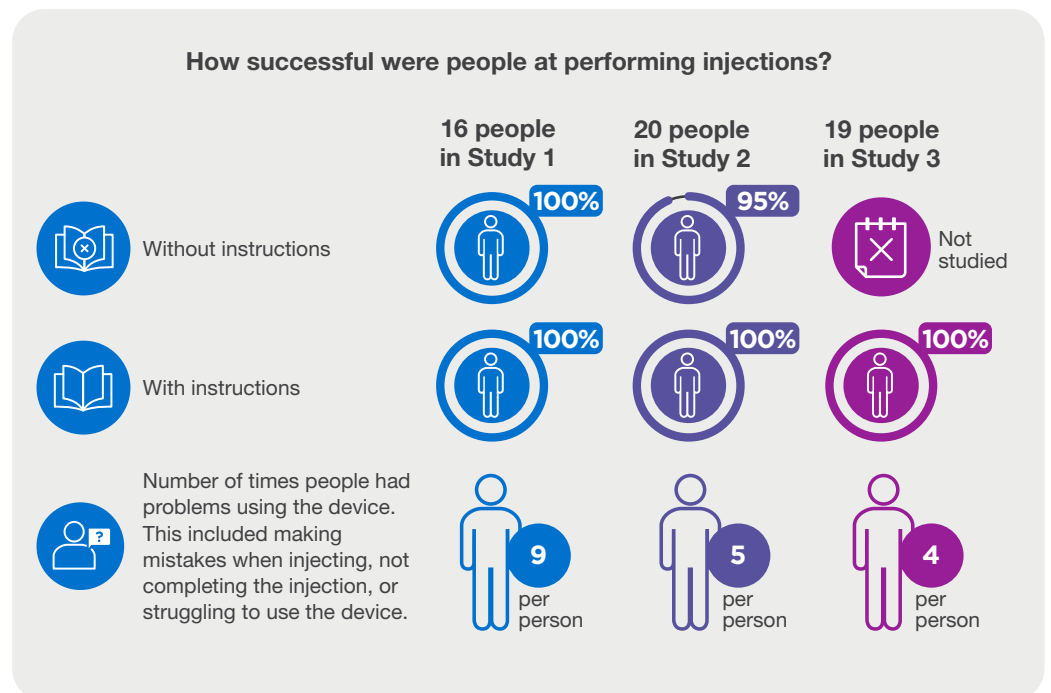
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- Researchers used people's feedback to improve this prototype. It was then used for the human factor studies.



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Human factor studies



- People in the later studies had fewer problems with using the device. This is probably because the improved design made it easier to use.

How did researchers improve the device using people's feedback?



Text and video instructions on the screen were simplified to help people inject themselves with the device

The injection button was colored teal and labeled to make it more obvious it was a button

Menu buttons were added below the injection button

The cancel/eject button was moved beneath the menu buttons

The battery was designed to last for about 3 years when used once a week

An arrow was added to the bottom of the device, where the needle is released. This was to help people hold the device the right way round during the injection.



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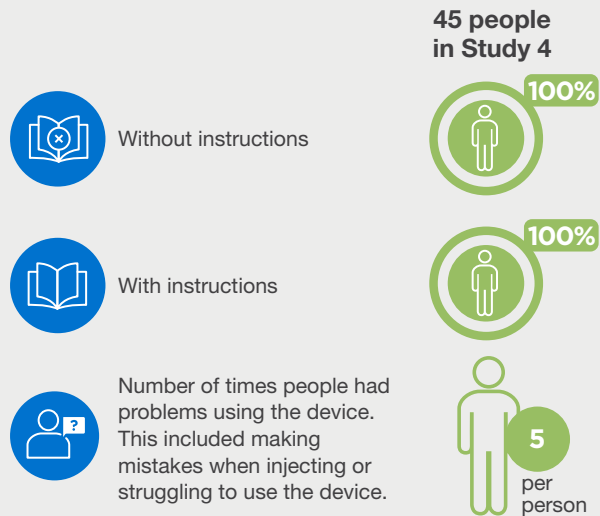
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How successful were people at performing injections with the final design in the last human factors study?



- After the final study, everyone who took part was able to correctly explain how the injection device worked.
- People were most likely to have a problem when using the device for the first time without using the instructions.
 - People who had problems using the device were successful when they performed injections again.
- None of the problems that happened during the injection process were harmful.
- Researchers made changes to the instructions and packaging to help people use the device correctly the first time.

Injury prevention study

- 25 nurses completed 500 practice injections without hurting themselves with the needle.
- The needle always went back inside the device and did not get jammed.
- The safety features of SmartClic/ClicWise were effective at preventing needle injury accidents.

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What were the main conclusions reported by the researchers?

- In these studies, people with chronic diseases, caregivers, and health care experts helped researchers design the SmartClic/ClicWise auto-injection device.
- People found the SmartClic/ClicWise auto-injection device safe and easy to use.
- Feedback from participants during all of these studies helped researchers to design the final device.
- This auto-injection device could help people to take their medicine more regularly and take care of their disease.

Are there any plans for further studies?

Researchers are studying the SmartClic/ClicWise auto-injection device and app in a separate study of people with chronic diseases. The aim of this study is to find out how easy to use and how effective people think the device and app are.

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Who sponsored these studies?

These studies were sponsored by Pfizer.

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Pfizer thanks all of the people who took part in these studies.

Scientific Article

Kyle Berman, Simon Moss, Barry Holden-Theunissen, Nobuhiko Satou, Kenji Okada, Mark Latymer, Attila Antalffy. Design Development of the SMARTCLIC®/CLICWISE® Injection Device for Self-Administered Subcutaneous Therapies: Findings from Usability and Human Factor Studies. 2023.

Acknowledgements

Writing support for this summary was provided by Jake Evans, PhD, at Engage Scientific Solutions, and was funded by Pfizer.