

INTRODUCTION

In order to assess effects of study drugs valid information on treatment compliance of patients is required. In routine clinical trials often paper-based diaries are used for this purpose which are inconvenient for trial subjects and have only limited reliability.

OBJECTIVES

- To develop, validate and assess a mobile app that is suitable to facilitate and monitor treatment compliance in trials

METHODS

- Customized, trial specific e-diary iOS apps
- Development of 4 different apps for 4 RCTs
- Data capture (photos) with dense (customized) time intervals
- Patient reported outcomes (NRS, QoL)
- Encrypted data transfer to CHDR server / into trial database
- Reminder functions
- Validation of each app according to GAMP 5
- Trial 1: 80pts 6w QD topical Tx of verruca vulgaris
- Trial 2: 36pts 4w QD topical Tx of atopic dermatitis
- Trial 3: 12 pts 12w QD topical Tx of uVIN
- Trial 4: 24 pts 12w QD topical Tx of genital warts

RESULTS

Full validation of all functionalities of 4 apps

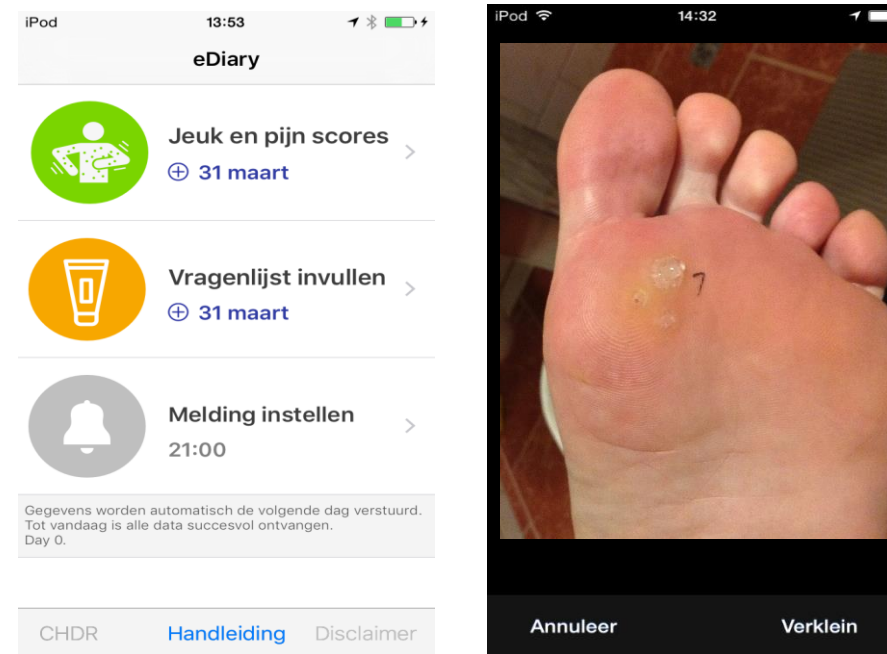


Figure 1. E-diary app screenshots in Dutch of eczema app (left panel) and for verruca trial (right panel)

Total patients N=152 in 4 phase 2 trials with demographics as specified in Table 1

Parameter	Verruca vulgaris	Atopic Dermatitis	uVIN	Genital warts
Enrolled	80	36	12	24
Age (SD)	25.8 (10.6)	24.9 (7.8)	49.8 (11.0)	34.4 (11.6)
Female	49 (61%)	27 (75%)	12 (100%)	9 (38%)
Male	31 (39%)	9 (25%)	0 (0%)	15 (63%)
BMI (SD)	23.5 (3.2)	22.5 (2.9)	29.2 (5.0)	26.51 (6.67)

Table 1. Demographics of four different RCTs with app evaluation

	Expected admins	Actual admins	Treatment compliance
Verruca	5882	5696	96.8%
Atopic dermatitis	1008	991	98.3%
uVIN	1598	1409	88.2%
Gen warts	1998	1710	85.6%

Table 2. Treatment compliance with the three different apps

- High treatment compliance in all four indications (Table1)
- Great acceptability in all four trials by different patient groups (Table2)
- Reminder function works effectively

How user-friendly was the app?	Very good	Good	Average	Moderate	Poor
Verruca trial	41%	55%	3%	1%	0%
Atopic dermatitis trial	74%	26%	0%	0%	0%
uVIN trial	27%	64%	9%	0%	0%
Genital warts trial	44%	39%	13%	4%	0%
Mean	47%	46%	6%	1%	0%
In general how would you rate the app?	Very good	Good	Average	Moderate	Bad
Verruca trial	19%	69%	11%	1%	0%
Atopic dermatitis trial	26%	68%	5%	0%	0%
uVIN trial	18%	73%	9%	0%	0%
Genital warts trial	22%	56%	22%	0%	0%
Mean	21%	67%	12%	0.3%	0%

Table 3. Patients' evaluation of the mobile apps

CONCLUSIONS

We successfully developed and validated electronic mobile patient diaries. Patients and researchers benefited from the app which is reflected by high acceptability, very positive patient-evaluations and very high treatment compliance rates.