Lessons learned from 16 years usage of mobile computers in clinical trials

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Abstract: For more than 16 years, mobile computers have been supporting the implementation of clinical trials. A review of 28 articles out of more than 100 clinical trials in which mobile computers have been used elaborates on the advantages and problems of this technology. A comprehensive overview of the various technologies as used in different settings is given, and then the methodology of using mobile devices in comparison to traditional methods is discussed. The considerations that need to be made and things to be avoided in order to conduct a successful clinical trial with mobile tools are listed in detail. This survey leads to the conclusion that mobile devices are very useful in most cases, especially when design and software validation aspects have been taken into account. Furthermore information is given about software validation aspects that are unique to the field of clinical trials.

Key words: software validation, clinical trials, remote data entry, mobile data capture, eCRF

1 Introduction

Technology has been used to support clinical trials for many years. Databases and statistical software packages were the first technological aids to be utilized, followed by computers for onsite data entry. Thereafter, network solutions such as the French Minitel or the German BTX (Bildschirmtext) were employed. In the meantime, the internet and especially the World Wide Web have become increasingly significant in clinical trials [SNF99, KO97] as well as in many other fields of business and science. Interestingly, a similar development can be observed with mobile devices. Nearly every mobile technology capable of data capture or data entry has and will be employed in clinical trials. A wide range of devices has been used, from the early programmable calculators and organizers [SAB85, TE89] to sophisticated pen-based devices with wireless data transmission capabilities.

2 Methods

A review of 28 articles out of more than 100 clinical trials in which mobile computers have been used elaborates on the advantages and problems of this technology. Only those articles have been included into the review, which gave a minimum of technical information about the mobile tools and methodology.

3 Results

Strikingly, research groups with profound experience in mobile computing in clinical trials reuse their hardware and software often; thus, sometimes several studies were carried out with the same technology. In such cases, generally the newer articles are listed since they usually contained the group's experience and referenced their previous work. There are two classes of articles: The first describes comparative articles in which previous ways of performing a clinical trial are weighed against new approaches using mobile computers, thus verifying the new methodology. The second set of articles describes the experience gained in clinical trials utilizing mobile technology. Several important aspects of the technology and methodology used are listed in Tables 1 and 2.

4 Discussion

Balas et al. [BAM96] emphasize the importance of time in the form of reminders or time-stamped data when using computers and the setting in which the computers are used. The superiority to not being reminded and to manual reminders has been shown in [SDB96] and [CA00] for desktop computers, which corresponds with our findings using mobile computers. Time series analysis and trend recognition have been used as well [LLC95, RWC01]. Handheld computers can greatly enhance the ease and quality of time-verified data capture [SHJ00], continuous quality improvement activities [HAR00], and adaptive therapies [SAB85].

The quality of data is improved in comparison to paper because the data are more complete [RWC01, BS00, HKA93], have fewer errors [KB96, LSD00], are more consistent [BBR93, Gup96], and there are fewer protocol violations [TE89]. Data editing, retyping, proofreading, and the process of clarification can be eliminated [BBR93, BS00, Gup96, TJC00]; irrelevant questions can be omitted [Gup96, MAB99].

Compliance is another important aspect. Time-stamped data contribute to improved compliance control [KB96] or allow for the assessment of compliance [BWC00, CLM92, HKA93, JRL01]. Results suggest that use of electronic data entry shows promise for improving compliance with long-term data collection [JRL01]. Even the least restrictive approach is a great improvement over paper, where there is no information at all concerning entry times, nor any control of them [TJC00].

Looking at the whole study process, an increase in efficiency [TE89, BS00] is found in most of the studies through easy storage and downloading of the data [MAB99] in combination with fast and easy data processing [KB96, TJC00]. The sponsor can perform analyses while the study is in progress. This facilitates the use of adaptive study designs. The devices and systems can be reused in several studies, where a single unit can be used repeatedly by different patients and investigators [MAB99], and other applications can be used simultaneously, e.g. food diaries and psychometric data collectors [SHJ00]. Thus, if the initial program is written in such a way that the questions asked can be changed in content and number to suit the study, it can result in greater adaptability and versatility of the tool; these features make it an ideal data capture tool for use in natural environments, the laboratory, and clinical settings [SHJ00].

Besides the above mentioned advantages of the use of mobile computers in clinical trials and in the clinical setting, a few disadvantages must be noted: Study centers and sponsors have to deal with technology (hardware, software and data exchange) aspects [LW98]. Sometimes there are large investment costs, but over a period of time the advantages outweigh the high initial costs (investments were: handheld computers, their peripherals, converting the questionnaire into computer programs) [Gup96]. Data must be downloaded daily (or at least sometimes) for backup issues [SHJ00]. A few patients found the screen difficult to see [TJC00]. Finally, additional effort is necessary to ensure electronic signatures and certified copies of electronic documents [FDA99].

A comprehensive overview from the sponsor's and investigator's perspective regarding comparisons of different data capturing and transmission techniques (e.g. pen and paper, handheld computers, fax, optical mark readers, voice, remote data entry, etc.) can be found in [LW98]. If a decision is made in favor of handheld devices, the following tips can be useful:

Two-way messaging available through the palmtop computer seemed to encourage continued use of the device. Patients stated that they felt that someone was closely monitoring their progress and they reported feeling as if someone cared about the information they were reporting [JRL01, TMK01]. Electronic diaries made the patients feel involved; written diaries were tedious [RMB96]. The use of other electric devices can be monitored [LLC95]. After protecting the device and the software so that no other implemented functions in the Psion 3a (here) could be used, the use of the handheld computers gene-

rally posed no problems [RHH99]. It is well recognized by medical staff that additional functionality such as the connection to the hospital information system, e.g. over a wireless connection, or lists of drug contraindications and interactions is advantageous. On the other hand, the additional functionality should not be confusing. If patients are to be the users, it could be helpful to encourage them to use the handheld computers for managing their calendars or address books, still the attractive applications of the devices. This could motivate them to accept the devices for daily use. That is only feasible, however, for studies running on the patient's private hardware or if the devices are dispensed to the patients for a long period of time, as with studies regarding chronic diseases where time series analysis is important [KGM00]. Another important aspect is ensuring that the ability and willingness to use an electronic diary is part of the inclusion criteria of the study – especially where the diaries are the main source of data [TJC00]. It is important to identify the team member(s) who assume(s) primary responsibility for survey administration [HAR00]. Members of nursing and medical staff should contribute to the development of the survey instrument to ensure that the necessary components are included [HAR00]. Use of a previously validated (pen and paper) survey instrument [HAR00] is recommended as a model for an electronic version. While desktop PCs interfere with the doctor/investigator-patient relationship, eCRFs on flat handheld computers, like paper, do not [TE89, BBR93]. Patient's and investigator's acceptance of mobile devices are widely documented [TE89, LLC95, BBR93, BWC00, Gup96, KMM01, MC00, TJC00, TSS95]. When compared to previous paper and pencil methods, those of mobile devices have been proven to be equal or superior [SAB85, LLC95, SHJ00, BS00, CLM92, HKA93, JRL01, KB96, LSD00, MAB99, RMB96, RHH99, SFB97, TMK01]. Finally, the most important points are brevity and simplicity of the user interface and input from those who rely on the collected data [HAR00].

Surely, the above mentioned advantages do not come without a price. Even as a study can have badly designed questionnaires or CRFs, there is no guarantee that there are well designed user interfaces nor that the software or hardware is free of errors and foolproof. This leads to the necessary reflection on software validation and standards. Interestingly, only two [TE89, RWC01] of the above listed articles mentioned their software tests and validations. In the mid 90's there was a discussion whether devices used in clinical trials should be treated as medical devices or not. This discussion led to recommendations for responsible monitoring and regulation of clinical software systems [MG97], influencing the point of view the FDA (Food and Drug Administration) later took. Their document entitled Computerized systems used in clinical trials"[FDA99] gives a good insight into the considerations that need to be made and the processes that must be implemented in order to set up and use computerized systems. Biebel [Bie00] stresses that risk management and software validation may appear to be a hindrance to product development, but they are in fact tools that support the development process. Used in the correct manner, they can even help speed up the process of producing better and safer software. For example, the V model can be used as a type of development life cycle. More about such models and software testing approaches can be found in [SC94, Kit96]. Should the new electronic system be audited, Stinchcomb [Sti98] describes in detail, e.g. using lists of questions, the necessary steps for carrying out such an audit.

While the worst case of a hardware or software failure is death where medical devices have been applied directly to the patients, as described in the case of Therac-25 [Neu95], a radiation therapy machine, this is different in clinical trials. For mobile devices used for data capture, biased data or data loss are the worst cases. These inconveniences can definitely be avoided or minimized using the procedures mentioned previously.

5 Conclusions

The many years of experience using mobile computers in clinical trials result in a few very important advantages besides the others listed above: *time, compliance, quality*, and *control*. Time stamping of data and the use of reminders enhances the quality of the rendered data significantly. Several studies, e.g. [SFB97, SS95], showed that one can not rely on the patient's memory and self-assessment, especially when real-time data gathering is essential. The better the data exchange between examination centers, patients and the study headquarters, the better the control of the study and the faster the response to aberrations and adverse events. From 8 KByte data packs (memory cards) used in 1988 [TE89] which were sent by regular mail to the sponsor and back, to collecting or sending floppy discs or CDs, to the use of computer networks, internet and wireless networks, the purpose of communication is more than just transferring the data to the statistician. If the patients have the impression that someone cares about them, as with the two-way messaging in [JRL01, TMK01], their compliance will be better as well. Communication technology is mature and stable and can be used even from the most remote areas of the world [OP97], and it is well known that mobile computers are capable of collecting data from patients in their natural environments [SS94]. Last but not least, the study is most likely to be carried out faster and better than with traditional methods.

Patients and medical staff usually have no problems using the devices if the program developers are familiar with basic software and user interface design issues such as minimizing free text entry or knowing how to manage text entry [WBR00] and the system is explained well to the end user. It is important to undertake the final test and validation with real patients in the study environment, putting the program designer into the clinical setting. This can lead to improvements of the clinical trial software and in turn enhance the data quality of the study.

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Technology	*Carried out/Publ.*	*Citation*	*Used Features*	*Main User*	*Site*	*Type*	*Field*	*Purpose*
Go Corporation Prototype with PenPoint-System	1991/1993	Beinlich [BBR+93]	pen-based	physicians as investigators	3 university clinics	experience	oncology	eCRF data entry, patients' and investigators' acceptance
Epson EH-400 with MS Windows for Pen	≤1999/2000	Berthelsen [BS00]	pen-based, internal timer	patients	university clinic	comparison (cross-over)	dentistry	patients' acceptance, data quality
MiniDoc electronic patient diary	≤2000/2000	Bousquet [BWv+00]	key-based, internal timer	patients	328 centers in 3 countries, home/daily life	experience	allergy	comparison of 2 strategies to treat seasonal allergic rhinitis, patients' and investigators' acceptance
In-house developed electronic diary card	≤1991/1992	Chowienczyk [CLM+92]	key-based, reminder, internal timer, transducer	patients	hospital	comparison	asthma	check of reliability of a conventional paper-based asthma diary card
Psion organizer II (model 250)	≤1999/1999	Clarke [CCGK99]	key-based, internal timer	patients	home/daily life	experience	diabetes	study of decisions to drive cars at various blood glucose levels
Psion LZ32	≤1997/2000	Greeno [GWS00]	key-based, internal timer, reminder	patients	home/daily life	experience	nutrition/ psychology	study of antecedents to binge eating
Programmable handheld computer, no information about type	1992-1994 / 1996	Gupta [Gup96]	key based	trained investigators	house-to-house survey	experience	tobacco survey	study of diversity and sociodemographic characteristics of tobacco use in Bombay, India
Atari portfolio	≤1996/1996	Harris [HBM+96]	key-based, internal timer, connection to physiological measurements	physicians, patients	hospital	experience	diabetes	investigation of the physiological responses to hypoglycaemia
PalmPilot	1998-1999/2000	Holdsworth [HAR+00]	pen-based	physicians and students as investigators	university clinic	comparison (cross-over), experience	oncology, pediatrics	computerized data collection system used for outcomes-based approach to antiemetic therapy in children

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Technology	*Carried out/Publ.*	*Citation*	*Used Features*	*Main User*	*Site*	*Type*	*Field*	*Purpose*
Psion organizers	≤1992/1993	Hyland [HKAH93]	key-based, internal timer	patients	outpatient clinic	comparison	asthma	Are symptom diaries of asthmatic patients inaccurate or based on retrospective recall?
Apple Newton Message Pad 100	≤2000/2001	Jamison [JRL+01]	pen-based, internal timer, telephone data transmission to study computer	patients	home/daily life	comparison	pain	reliability and validity of electronic diary data, patient compliance, comparison to paper and phone interviews
PalmPilot, Palm III, Palm IIIe, Palm m100	2001/2001	Koop [KMM01]	pen-based	patients	resident doctor	experience	allergy	placebo vs. drug, double-blind clinical trial
Programmable handheld computer, no information about type, likely Psion	≤1995/1996	Kos [KB96]	key-based	patients	home/daily life	comparison	smoking and dietary intake	reliability of electronic food diary
Palm IIIx	≤2000/2000	Lal [LSD+00]	pen-based	students as investigators	university clinic	comparison (cross-over)	burn data collection	time for data collection and error rates against paper and later entry
PIPER (Prompting Intensity of Pain Electronic Recorder, in-house development)	≤1994/1995	Lewis [LLC95]	key-based, internal timer, reminder, connection to TENS-unit	patients	university clinic and home/daily life	comparison, experience	pain	reliability and validity of PIPER pain ratings, comparison with paper visual analog scale, patients' acceptance
MiniDoc electronic patient diary	≤1998/1999	McBride [MAB99]	key-based, internal timer	patients	university clinic	comparison	hospital quality outpatient survey	Are handheld computer data collections introducing bias or increasing respondent difficulty?
Palm III	1998-1999/2000	McLaws [MC00]	pen-based	infection control professionals (ICPs)	9 hospitals	experience	nosocomial infections	test of a hospital infection standardized surveillance, including electronic data capture
Compu-Void, in-house development	1990-1995/1996	Rabin [RMB96]	key-based, internal timer	patients	hospital	comparison (cross-over)	urology	patient preference and compliance, data quality
Palm IIIx	1999-2000/2001	Reilly [RWC01]	pen-based, internal timer	pharmacists	hospital	experience	pharmacy	monitoring pharmacists' interventions
Psion 3a	1995-1996/1999	Rose [RHH+99]	key-based	patients	university clinic	comparison	psychology, psychosomatics	to test substitutability of paper-based instruments, time for data collection, data quality

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Programmable handheld computer, no information about type	1992-1994 / 1996	Gupta [Gup96]	key based	trained investigators	house-to-house survey	experience	tobacco survey	study of diversity and sociodemographic characteristics of tobacco use in Bombay, India
Atari portfolio	≤1996/1996	Harris [HBM+96]	key-based, internal timer, connection to physiological measurements	physicians, patients	hospital	experience	diabetes	investigation of the physiological responses to hypoglycaemia
PalmPilot	1998-1999/2000	Holdsworth [HAR+00]	pen-based	physicians and students as investigators	university clinic	comparison (cross-over), experience	oncology, pediatrics	computerized data collection system used for outcomes-based approach to antiemetic therapy in children

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Citation	*System details (size: length, width, depth, weight)*	*Software details*	*Training*	*Quantity of data*	*Results*	*Problems*
Beinlich [BBR+93]	275 × 212 mm, pen only, handwriting recognition	eCRFs "identical" to paper CRFs	study monitors: 1 day; investigators: 1 day; user handwriting training procedure: 2 h	20 patients, 798 data points per patient	avoid long text entries, capture free comments in handwritten form without transcription, almost no problems for interviewed patients, investigators needed more time for eCRFs than for CRFs, but time savings occur later	hardware slow, screen contrast poor
Berthelsen [BS00]	210 × 226 × 25 mm, 1 kg, pen only	additional help through explanations, timer used to get duration of use, written in C++	short patient training period	50 patients, 78-item questionnaire	73% preferred computer over paper in future use, help feature used only once	5% inconsistent answers between paper and computer
Bousquet [BWv+00]	140 × 178 × 26-38 mm, 522g, 4 keys only	data items are time-stamped	no information	328 centers enrolled, 258 centers recruited 469 patients, >330 data points per patient	patients: acceptance high, investigators preference: 60% computer diary, 14% paper diary, 26% no preference	no information
Chowienczyk [CLM+92]	4 keys only	data items are time-stamped, reminder alarms	no information	33 patients, 21 data points per patient	25% false entries on paper diary cards discovered	data loss in 3 cases
Clarke [CCGK99]	about the size of a handheld tape recorder or dictaphone	internal timer used to check a 45 s - period constraint	training given, but duration unknown	158 patients, 1000 data points per patient	only medical results published	no information
Greeno [GWS00]	142 × 78 × 29 mm, 250 g, keyboard with 36 keys	data items are time-stamped, reminder alarms	60-90 min individual instruction, 2-3 days practice period, 30-45 min practice follow-up	79 patients, 4689 data points altogether	only medical results published	no information

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Citation	*System details (size: length, width, depth, weight)*	*Software details*	*Training*	*Quantity of data*	*Results*	*Problems*
Gupta [Gup96]	size: no information, 290 g	no information	training for investigators given, but duration unknown	99598 people interviewed	using handheld computers to collect data in the field was successful	no problems even with high temp. and high humidity
Harris [HBM+96]	103 × 197 × 29 mm, 495 g, box for transducer: 190 × 100 mm	data items are time-stamped, written in C	no information	6 months, mostly for overnight measurements, data sampling: 2 min every 10 min.	system was robust and reliable, system can be used to monitor changes in heart rate, blood flow, skin temperature and sweating	movement artifacts had to be filtered out
Holdsworth [HAR+00]	120 × 81x 18 mm, 162 g	Pendragon forms; incomplete surveys kept as reminders; check-boxes preferred	Clerkship students as investigators: 2 days	in routine use; for time and motion study: 10 trained investigators, data of 20 patients per investigator	total of 48 % time savings getting data into the database, use of handheld computers became standard procedure and was well accepted by patients and their families	no information
Hyland [HKAH93]	no information because types of Psion organizers used were not given	data items are time-stamped	training for patients given, but duration unknown	24 patients; 84 data points per patient (14 days, 3 peak expiry flows, twice per day)	quality of diary completion is often poor; electronic, time-coded diaries could provide a better method for ensuring the quality of diary records	no information
Jamison [JRL+01]	184 × 114 × 27 mm, 400g	support of two-way messaging: download of data (time-stamped) and patient notes, sending messages back to patients	patients: 1 h, telephone support available	Total of 36 patients; 20 patients kept electronic diaries for one year, ¿16 data points per day	data from electronic diaries are both reliable and valid; patients using electronic diaries preferred them to paper diaries and showed much higher rates of compliance and satisfaction	malfunction of 2 units leads to replacement; loss of 7 days of data; one unit damaged but no data lost
Koop [KMM01]	120 × 81 × 18 mm, 170 g	Waba 1.0; use of internal datebook, data items are time-stamped	patients: 5-10 min. study nurse: 2 days training	12 patients; on 4 days data entry for 4,5 hours every 15 min, 5 data points each time	increase of data quality compared to similar studies; substantial time-savings to closure of the database; high patient acceptance	program crashed six times out of 903 data entries; not data lost
Kos [KB96]	142 × 78 × 29 mm, 250 g	180 food items organized as two-level menu	training for patients given, but duration unknown	82 patients; 4 days; 6 measurements per day	handheld computer well accepted by patients; good reliability	no information
Lal [LSD+00]	120 × 81 × 18 mm, 170 g	Pendragon forms; forms ïdenticalto paper forms	no information	3 students as investigators; 110 medical charts; 18 variables	Palm method is faster (23%) and more accurate (58% fewer errors) than manual method	no information

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Citation	*System details (size: length, width, depth, weight)*	*Software details*	*Training*	*Quantity of data*	*Results*	*Problems*
Lewis [LLC95]	60 × 110 × 30 mm, 160 g, 7 keys only	data items are time-stamped	short patient training period	study 1: 40 patients, 7 data items; study 2: 36 patients, 4 times daily for 2 months	good validity and reliability shown, electronic diary was well accepted even by elderly patients	some data missing because of human or equipment failure
McBride [MAB99]	140 × 178 × 26-38 mm, 522g, 4 keys only	data items are time-stamped	no information	349 patients; 31 questions per patient	electronic diary method is highly acceptable and produces results comparable to paper forms	evidence of lower internal consistency reliability with electronic diary, likely a design problem
McLaws [MC00]	120 × 81 × 18 mm, 170 g	drop-down list for selection of all variables except dates and duration	methodology and technology training for infection control professionals: two 1-day workshops	9 infection control professionals; 1 year; > 200000 data points altogether	7 of 9 sites consider electronic handheld data capture a useful tool; near 100% completion of necessary data; useful for large data sets	initial difficulties in adapting to the new technology
Rabin [RMB96]	size: no info; LCD-display: 21 lines, 32 characters, keys: 7 + 10 digits	data items are time-stamped	carefully instruction of all patients; written instructions for reference	72 patients; 2 weeks; 10 data points per day	very high preference for electronic diary; more events reported using the computer than the paper diary	electronic diary is bulky
Reilly [RWC01]	120 × 81 × 18 mm, 170 g	Pendragon forms; data items are time-stamped	one-on-one training to the staff, 1 h each; developing pharmacist available for support	12 data items for each intervention; test: July 1999 to April 2000, since then in routine use	staff pharmacists were enabled to gain ongoing data which was too time-consuming before	in the beginning staff pharmacists expressed discomfort with the new technology
Rose [RHH+99]	88 × 165 × 23 mm, 280 g	ComBas 1.3, inhouse development	questions used are self-explanatory; technical training: no information	1400 patients; paper: (1/1989-12/ 1994) 354202 data items; computer: (1/1995-12/ 1996) 420723; since then in routine use	no problems even with elderly patients; time reduced by 2/3 spent on documentation; 50% cost savings; no differences seen in stability coefficients and data distribution	use of computer is limited for patients with severe visual disorders

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Citation	*System details (size: length, width, depth, weight)*	*Software details*	*Training*	*Quantity of data*	*Results*	*Problems*
Schrezenmeir [SAB+85]	86 × 195 × 25 mm, 375 g	data items are time-stamped; additional security-related programs	no information	3 months; 12 patients; data input ≥4 times per day	computer-assisted meal-related insulin therapy seems to be superior to conventional therapy; well accepted by patients	no information
Straka [SFBS97]	looks like ordinary amber pill bottles, but with slightly larger caps	data items are time-stamped	short instructions were given	55 patients took medication 3 times per day for 21 days	patient-kept diaries statistically overestimate actual compliance; MEMS is more objective than patient diaries	the system cannot guarantee that medication was swallowed
Stubbs [SHJ+00]	203 × 101 × 29 mm, 480 g, size of Psion organizer: no information because type not given	data items are time-stamped, reminder alarms	no information	several studies; one with 20 patients over 2 days; data given hourly between 8:00 a.m. and 11:00 p.m.	paper-based VAS (pbVAS) and electronic VAS (eVAS) should not be used interchangeably in the same study; eVAS are reproducible relative to pbVAS but seems to have limited use regarding the scale ends; preferences (eVAS, pbVAS, no pref. in %): Study 1: 57, 13, 30; Study 2: 38, 54, 8; Study 3: no differences	no information
Tattersall [TE89]	140 × 80 × 30 mm, 250 g, keyboard with 36 keys, 8 KByte data packs for postal transfer	to advance to next question, each question has to be answered first; built-in programming language OPL	1 h briefing session on the computer and program; written guidelines given	8 general practitioners treated 15 patients; 3 visits per patient in one month	physicians stated that the use of the organizer had no effect on the consultation; text entry was not used, so sometimes it was necessary to key in codes from paper lists, preference: 5 computer (if lists are included), 1 paper, 2 no pref.; bigger display desired; thus: using handheld computers is possible and reliable	present coding of symptoms was found to be a major drawback; several minor problems detected

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Citation	*System details (size: length, width, depth, weight)*	*Software details*	*Training*	*Quantity of data*	*Results*	*Problems*
Tiplady [TJC00]	MP110: 198 × 105 × 30mm, 580 g MP 2000: 210 × 119 × 28 mm, 635 g	data items are time-stamped; no retro-spective entry	inclusion criteria used data recorded in the diaries du-ring the two-week run-in period	3 countries; 135 patients; two months; each patient visited the study centers 4 times	data handling was substantially faster than in similar paper-based studies; data collection was very satisfactory (86% patients had completed diaries); 17 of 19 investigators would use the electronic diaries again	two devices failed (out of 150) and were replaced; infrared beaming for data transfer was problema-tic, replaced by PCMCIA storage
Totterdell [TSS+95]	142 × 78 × 29mm, 250 g, keyboard with 36 keys	reminder alarms	training given, ≥1 day practice of the tasks before start; telephone support	61 nurses for 28 days; several self-rating scales; sleep diary; bihourly performance	compliance rate for end-of-day mood measures: 85%; for sleep diaries: 95%	no technical or acceptance pro-blems
Tsang [TMK+01]	size of a typical organizer with screen opening over the keyboard	support of two-way messaging: down-load of data, sending back analysis to pati-ents	training given; trial period of 2 weeks	19 patients; 6 months; data about meal infor-mation	significant benefits for diabetes con-trol detected; patient's opinions: easy to use 95%, useful 63%	technical pro-blems during the early part of the study
van Gerven [vSJ+96]	140 × 178 × 26-38 mm, 522g, 4 keys only	data items are time-stamped; reminder alarms; no retrospec-tive entry	group training (2-10 patients) for thorough study instructions and diary practice	159 patients returned 1407 visual analog scale (VAS) scores and 452 headache relief ratings (HRR)	1.5 % of total data were omitted or corrected using a paper form; even if patients desire it, it is unnecessary to backup electronic patient diaries with paper-and-pencil methods	5 HRR sco-res (1.1%) and 3 VAS scores (0.2%) were lost

Tabelle 2: Technical details and results of mobile computing technology used in clinical trials (ordered by first author)