Royal College of Surgeons in Ireland





Pediatric weight management through mHealth compared to face-to-face care: cost analysis of a randomized control trial

AUTHOR(S)

Louise Tully, Jan Sorensen, Grace O'Malley

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treatmenteither thoug usual care (hee additional facet of ace boostersessions with the multidisciplinary teameither thoug one to one sessions or goup sessions) or remotely in the metalth app facti vate) [3]

DataCollection

Participant data including trial goup data, whether tby commenced onetoone or goup treatment,tb number of sessions attended, and records of treatment completion or withra wal stags, were collected during the trial and used for ths analysis to ascertain variations in costs per patient. Ost data were obtained from multiple sources. For facetof ace maintenancesessions, we used a timedri ven actiitybased microcostingmetbd [8] to capturetb direct costs associated with the facetof ace time of halth care professionals with patients. We also included administrative time associated with appointmentpreparation. We interie wed personnel to map workflow processes associated with usual care to accurately assess the unit costs of process appointments and dropout/nonattendancecosts. A record of the trial costs was maintainedby the principal investigator and it included invoices received for contracted mebilth serice delivery, the related epenses, and the time allocated for checking in, monitoring and processing participants. During baseline data collection, parents carers were asked to proide details of their annual income, currentoccupation, the make and model of their car (f any) mode of transport and distance traveled to attend bspital

CostAnalysis

appointments.

We carried out our cost analysis based on the detailed unit costs for providing care to both study goups from the perspective of the publicly funded balth care system. We undertook the cost analysis underpragnatic realw orld^o conditions and their cost implications (e, estimates of implementing the intervention outside of a research trial) [9] as the trial costs included additional expenses that would not represent the cost of telemedicineif proided as part of usual care (g proision of smartpbnes and mobile data packags to trial participants) We calculated the cost of staff time according to local gidance [$2 \cdot 2$] adjusting for payrelated social insurance, pension contributions, annual leave, and overbads. Salaries were calculated using the midpoints from the salary scales for the trial period [2] For the cost comparison assessment, we also included eqipment frequently used for clinical appointments. unit costs and breakdown of these areash win Mitimedia

pendix 1. Variations in the costs allocated to individuals werebased on their treatment pup, the completion status, and the number of weeks sessions completed.

We also undertooka budgt impact analysis to assess the cost of providing the metalth intervention to all eligble adolescents (new referrals) over a fronth period. In the sensitive analysis, we evaluated cost assumptions by changing the base case parameters, such as the annual cost of software maintenance, eqipment, and variations in the time spent by elin monitoring and supporting adolescents in the metalth arm. We also examined the impact on the cost per adolescent by changing the optimum treatment cobrt size by varying the annual number of users.

We assessed the costs incurred by families based on prospectively collected trial data, but these were not included in the main cost comparison owing to by levels of missing and incomplete data. Herefore, the study considered only the shorth costs incurred by the publicly funded balth care system.

Results

h total, 9 adolescents and thir families provided consent for participation in the trial; only 8 participants completed the trial as 8 adolescents with the w from the study (6 from the usual care goup and 2 from the metalth goup) after allocation, as shown in figre 1.



Figure 1. Trial allocation and completion among participants with base case cost estimates.meblth mobile balth



HealthCare SystemPerspectie Costs

conversionrateforthe referenceyear a was
 We estimated meandirect cost peradolescent completed onetoone usual care in the maintenancephase of treatmentat
 for all the sessions, as shown in Table 1. For an adolescent participated in goup maintenancesessions, the cost was estimated at a (assuming a makmum capacity of families per goup) With a wal or partial completion costs ranged from 5 to 7 peradolescent for onetoone sessions depending on the number of sessions missed; with a wal costs

for the in the goup treatmentwere estimated at 3 as thir place in the goup was lost and could not be filled by another patient. For adolescents we were randomized to use the metalth systemand we completed the program, the mean cost per adolescent was estimated at 3 (based on the intention to treat cost dided over all the adolescent sallocated to the metalth arm; n_{5} Withdra wal from or partial completion of the metalth intervention was estimated to cost 3 to 6 depending on when the participant dropped out (see Mitimedia Apendix 1)

Table 1. Ost per adolescentby treatmentgoup.

| atmentgoup Etimated direct cost per participant, mean \$D) | |
|--|------------|
| sual care (netoone progam) | 8 <u>¥</u> |
| sual care (pup progam) | 3 jž |
| mealth ^a | B Ma |

^amealth mobile ealth

Ecountingfor partial completion and attrition costs, the mean
cost incurred for the usual care arm was 24 \$D \$2
(pup participants: mean 3 SD 22 onetoone
participants: mean 7 SD \$2
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T costs for the design and development of the metalth serice (website and app domain name registration and bsting ideograph y, iconograph y, deice updates for firmware, app development, maintenance costs, and cloud bsting were independent of the number of users. The sensitizty analysis sb wedthat the main driver of costs for the metalth goup was the B time spentmanaing the metalth serice arm of the trial platform administration, indiidualized care plans, proiding feedback, troublesboting cacking in) The was estimated to be approximately 2 burs per adolescent over 6 weeks (approximately 5 minutes per adolescent per week) during the trial. Sensitility analysis sb wed that the would need to be reduced to 5 burs & minutes per adolescent per week) with the number of users increased to 6 before the cost per person would match that of one to one, in person care (6)

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per participant) firther , we tested our assumptions around the estimated costs of software maintenance and datastorag costs per annum though increasing these by the cost per adolescent for the metalth arm (h > by 0) which became negative once extrapolated to larg numbers of users and had a negative impact on the cost comparison with usual care.

BudgetImpact

sing the cost per adolescent wb completed the metalth intervention and considering the capacity of the weith managment serice to be **Q** new patientreferrals per year, we estimatedthe budgt impact of offering the maintenance pase of treatmento all elighte adolescents a ≥€h centile) face to face instead of using mealth from the perspective of the balth care system. Offering pase 2 of the facetof ace treatmentoeachelighle adolescentwithobesityusing the base case as a direct cost of approximately wereas te would cost 🖗 é «luding mealth serice app development costs) A such the direct budgt impact of replacing facetof ace maintenancetreatmentand offering the mealth intervention to all elipple adolescents in one year would be 🛛 witbut accounting for potential cost and time saing to be gained by offering mealth care only.

Family Perspectie

O the families who took part in the trial, 🕉 🖉 proided details about thir travel, work, and schol arrangments for attendingclinical appointments firthr , 🌮 of the Ð families used public transport at a mean cost of 7 perbspital isit (ang **1**) whereas 3% families drove an average of 7 km (rang 🔒 km) to their inperson appointments.costing approximately 1 each way based on a preious study estimating the cost as Ø per kilometer including running costs and depreciation [2] plus a 0 burly parkingfee) h addition,4 out of 9 families **%** took a tak, with a mean cost of 2 each way (ang -515 **bing** the data provided, the mean cost of travel to and from appointmentsperadolescentwas 8 perisit (6 for the full facetof ace maintenancepase)

of the adolescentshad missed school Girtermore, 🛣 🗿 for their appointmenton the day of clinic, with an average of 3 burs missed (aning from @ minutestoth full schol day) A for parents, 2% reportedtat te y neededto take time off from work to attendtbir chd's appointment frong tese 2 parents,7 neededa full day off and 1 reqired closer to all f a day off; the others did not provide details. O these wb regired timeoff, 8 parentsreportedtbir annualincome, with7 earningless tan 0 perannumand3 others earning less tan Ø perannum.h addition,4 parentsearnedmore tan (9 per annum and 4 did not report their income. mean daily salary adjusted to the whole time eqi valent) per parentwb proided details of their income was 2 median Ø

Discussion

Principal Findings

ts study assessedta treatment osts based on trial data from a pragnatic noninferioritypilot ℝ. There was a ‰ attrition rate for the trial the b wever, the is broadly in line with pediatric ℝ [2] and weith management interventions in gneral [6] where dropouts are commonowing to the intensive nature of these interventions.

results sb w that the metalth intervention, developed Æ using eidencebased approaces, is associated with ligr ealth care costs tan facet of ace pediatric weig management. h desig of the trial was such that all adolescentsattended facetof acetreatmenbeforerandomiztion to either the digal or facetof ace maintenance pase; therefore, the partially digal intervention arm incurred appointmentand mealth costs. sensitity analysis results demonstrated at if rolled outto a largr number of users, the main driver of the costs for the metalth armis the staff cost related to B monitoringand support on a weekly basis. f the metalth serice were to be automated it could be to reduce these costs; b wever, further studies would be regired to epolore the clinical impact of delivering the metalth serice to the clinical population with inputs from lesse perienced clinical staff or ia increased automationand the associated etical considerations.

ComparisonWith Prior Work

W finding that staff costs are the most sensitive drivers of the overall cost has been shown in economic evaluations of mehlth in other fields, including care after pregancy termination [2]. We also found that substantial costs were incurred by the families, but we were unable to fully explore the costs from the perspective of parents and families owing to incomplete data collection. If we ver, the is an important consideration for future research as assessing ways to reduce in equilities that may be excerbated by the burden of attending facetof ace appointments crucial. It is important to explore ways to collect cost data from families, which does not substantially add to the burden of participating in research

Pe ious studies la ve demonstratedtlat families wb live further from clinics, or for whom travel to inperson appointmentsis more burdensomeor complex tend to ie w telemedicinemore favorably $[\mathbf{Z}]$ Despite the most published economicevaluationsof telemedicineconsidertb perspectives of only the health care sericepro ider, as shown for cardiovascular disease managment [8] obesity prevention [6] and elealth more broadly [2] t is important for researcers to assess delivery costs for future evaluations of digally delivered pediatric weig managment to build an eidence base for the population with unique care needs [0] t is also ital that economic evaluations adopt a societal perspective to capture costs apart from direct balth system as been recommended for mealth in caring for costs. Is tb elderly as well [3] E financial strain on parentscared versis a documented barrier for pediatric chonic disease managment [2] and access to clidbod obesity treatment[3] particularly in rural communities[3] Alson and colleages also reportedtat a telereabilitation progam

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was not costef fective for patients recovering from hp replacements but that the reduced burden on patients and careg vers was notable[5] finical pediatric populations are comparable in that patient and careg ver time as well as travel are reqired for appointments bl wever, digtal interventions may also incur further costs for families, some of which we did not capture, such as internet and pbne bills that were covered with the research budgt but would add to the burden on families. Is higgs the need for further cost studies incorporating a wider perspective that is not limited to the balth care proider.

h gneral, the economic eldence for metalth is mixed [6] t is an emerging field, and much of the work to date as evaluated mealth for **balt**h promotion or in the selfmanagment of chonic conditions to prevent the need for balth serice usag. Such studies are not directly comparable with ths trial that evaluated an eidencebased adolescent obesityinterventionregiring consistentappointmentattendance with an obesity intervention deliveredia an mealth platform as a remotealternative. body of work associated with the development and testing of the Bacti vate mealth system [3 -5 ,7] has provided novel evidence for the feasibility of $using \textit{mealth} \ \textit{for pediatricweig} \ \textit{managment with transparent}$ accounts of the limitations identified, including the relating to the collection of cost data, which will be valuable for informing the desig of future robust trials with the ulnerable and complex population.

A recentscoping rele w [3] on the use of elalth in diabetes critical issues such as staff training monitoring care inited techologial infrastructuresupportand maintenance and b w tese differ by settingand intervention. Abug te mealth interventiontat we evaluated for the maintenanceplase of the treatmentdid not prove economically iable in its prototype form, our results point to desig and development aspects where amendmentsmay produce cost saing. A needfor 5 minutes of 🖯 time per participant per week may be a modifiable interventioncomponent Or study assessed to costs based on the time spent by a senior reistered pediatric physiotherapist; b wever, the option of a more unior staff membermanaing the mealth intervention may be feasible, or there may be scope for automating some of the tasks, such as feedback on engagment with the app.

hput from families and E involved in the serice could further help identify the acceptability of such modifications. Erther , the option of offering both pases of treatmentia the mealth intervention may present a more economically attractive alternative to facetof ace treatmentaltbub their clinical effectiveness is unknown. Information b w the option mit suit patients with less complex obesity and fewer complications or comorbidities may also yield eldence for its appropriateness acceptability of receiing only remotecare for adolescent obesity is also unknown; b wever, when the mealth trial was being desiged, most families specified a preference for some facetof ace care. To was considered during the design of the pilot R . More recently, during the 0 0/9 pandemic, up to % of families refused irtual appointments from the 6d and **d**olescent Weit and preferred to wait longr for Magment Serice

facetof ace care. Otwitstanding the preferences of families wb are already engagd in treatment thre may be scope to increaseaccess to care thoug using the metalth platform with families wbse access to eidencebased obesity treatmentis limited (g choren and adolescentswb live in rural areas, tbse wb may ag out of eligbility for pediatric balth care, or tbse wb a veno local pediatricobesity treatmenterices) t may also be possible to ache ve cost saing by proiding earlier access to treatment ia the mealth platform to adolescentsin the community setting and negate the need to pin a waiting list for a Tier 3 obesity serice. Erlier interventions can reduce or prevent obesityrelated complications; g ven the promising preliminary data on the clinical effectiveness of the mealth system [7] offering such care to adolescentsmay mitigate the balth effects of obesity at a crucial time during their development.

Limitations

ΪĒ study ad several strents and limitations. As essing the costs incurred by both treatmentarms alongide a pragnatic pilot **R** was an important strenth of the study, as it reflected the actual costs of delivery in a realw orld clinical settingand allowed assumptions that were underpinned by clinical epseriences. microcosting analysis also enabled detailed and accurate direct costing for usual care with the pediatric weig managment serice. I wever, the study did not meet the target recruitmentnumberwith the available time period, and coupled with the attrition rate, the led to insufficient power for demonstratingstatistically sigif icant noninferiority h addition, low response rates for baltrelated galityoflife measuresused contributed to the decision of undertakingonly a direct cost comparison. A a result, our cost analysis does not proide a full economicevaluation Erther , althug it was the only treatmentcenter available nationwide, we acknowledg the limited external validity of our finding given the recruitment thoug a singe centerfor obesity management. Ost was also not a prespecified outcome for the trial and the study was undertalen as an epiloratory analysis after completion of the trial.

bhetbless, it is importantto proide transparentaccounts of studies undertalen to assess mealth interventions with the clinical population, for whom no preious cost studies be been undertalen. It is especially pertinent to document data to describe the economic inbility of mealth which is often presumed to be a costs a ing alternative to traditional care [8] g ven the emphasis on digal interventions with the European digal balth strateg [9] compounded by the slift in processes resulting from the O D/9 pandemic.

h addition, access to treatmentfor obesity is severely limited in reland and elsewhere with only approximately % of primary care proiders reporting sufficient capacity to offer treatment[3] Therefore, developing and evaluating metalth interventions for obesity is a the priority for batch serices. The preliminary research will allow for improved processes and desigs aiming to makinize resources whe maintaining clinical effectiveness and acceptability among users.

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Conclusions

62dbod obesity remains a leading concern in public balth and balth serices, and the lifetime societal costs have been sb wn to be substantial [4] t is important for researchers and practitioners to find new ways to improve the reach and effectiveness of treatments to ensure equable care. The analyzed digtal approach implemented for the maintenance phase of weigh management, was over four times more expensi ve to deliver than facetof ace maintenancesessions in a pilot \mathbb{R} . We implemented outside a clinical trial, this cost is likely to reduce owing to the economics of scale and lower costs associated with techolog usag. Or results high the importance of conducting further research to explore the cost of fectiveness of eldence-informed metalth interventions in treating chonic diseases such as obesity across multiple centers.

Acknowledgments

study was funded by the 🔓 bi versity of Micine and Halth Sciences - StR progam (ant # ΪĒ and carried out as partofte ealth esearch Bard B S₽₽ trainingprogam \$ a randomized controlledtrial on witch tis study was based was funded by the B and the füdren' s End for health & Artional füdren' s Research entre of reland PAK fundershad no role in the design of this study including the collection, analyses, or interpretation of data, or in the preparation of the manuscript. We are gateful to Pofessor Ananda Barls for her supervision and gidance duringta desig and development of the Pacti vatetrial and the planning of the cost analysis. He authors wish to acknowledge all the staff at B Temple Street, especially the B teamwb facilitateddatacollection for ths study, as well as the study participantsand families for their time.

ConflictsofInterest

🛚 senior autor 😡 🛛 led the design and onging development of the Eacti vate system.

MultimediaAppendix1

Developmentof unit costs.

[DØ ffe, 0 8 - Mitimedia pendix 1]

MultimediaAppendix2

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Abbreviations

HCP: **balth** care professional mHealth: **mobile balth** RCT: **randomizd controlledtrial** SDS: **standardizd detation** score

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