

CORE HEALTH OUTCOMES IN CHILDHOOD EPILEPSY (CHOICE): PROTOCOL FOR THE SELECTION OF A CORE OUTCOME SET

ARTICLE PUBLISHED IN



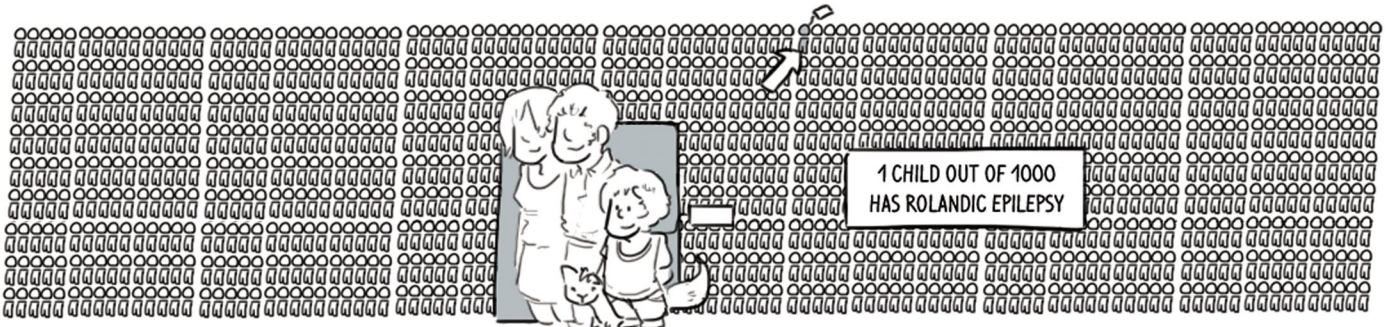
ON NOVEMBER 28, 2017



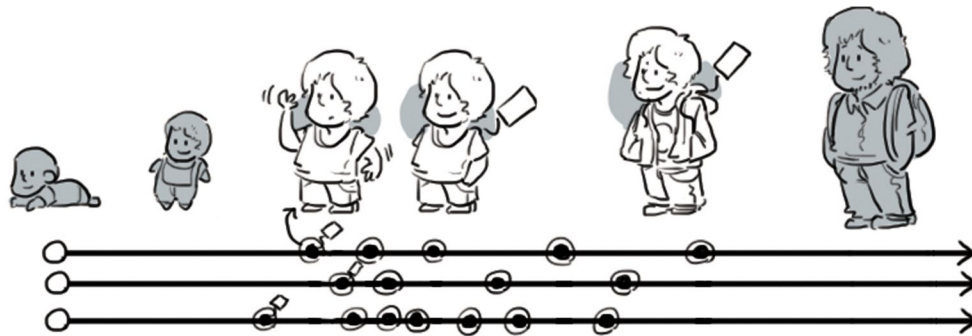
INTRODUCTION



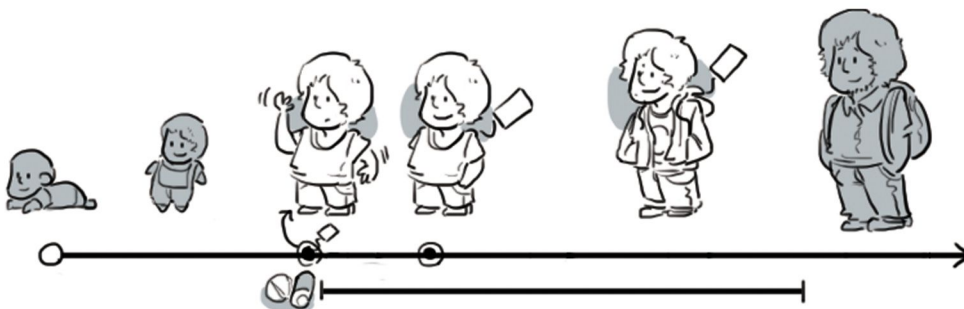
PEOPLE WITH EPILEPSY HAVE RECURRENT SEIZURES (EXCESSIVE BRAIN ACTIVITY) WHICH CAN MANIFEST IN DIFFERENT WAYS INCLUDING UNCONTROLLABLE CONVULSIONS.



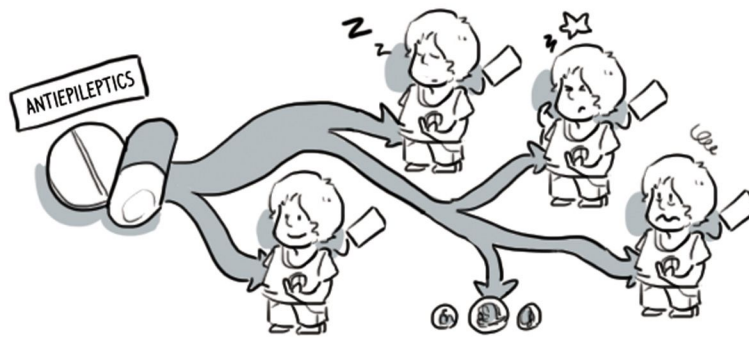
ROLANDIC EPILEPSY IS THE MOST COMMON TYPE OF CHILDHOOD EPILEPSY AND AFFECTS 1 IN 1000 CHILDREN.



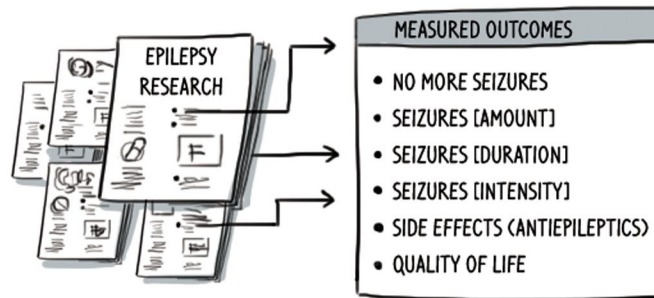
ROLANDIC EPILEPSY SEIZURES TYPICALLY APPEAR AROUND 7 YEARS OF AGE AND CEASE BY ADOLESCENCE.



THEY CAN USUALLY BE CONTROLLED WITH ANTI-EPILEPTIC MEDICATIONS...



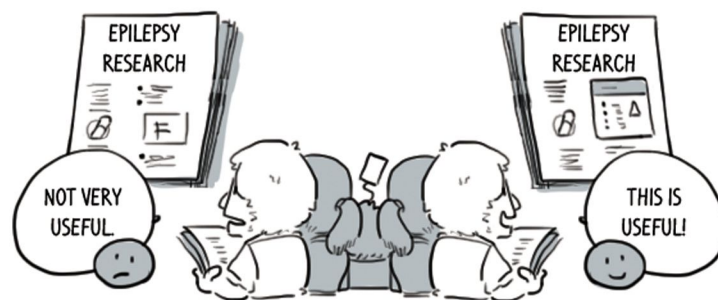
...WHICH ARE KNOWN TO SOMETIMES LEAD TO SIDE EFFECTS SUCH AS SLEEPINESS, BEHAVIOR PROBLEMS, HEADACHES, NAUSEA, DIARRHEA AND FATIGUE.



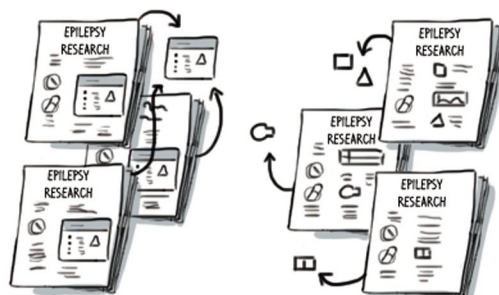
PREVIOUS RESEARCH STUDIES EVALUATING INTERVENTIONS [=TREATMENTS] FOR EPILEPSY USUALLY FOCUSED ON THE FOLLOWING OUTCOMES:



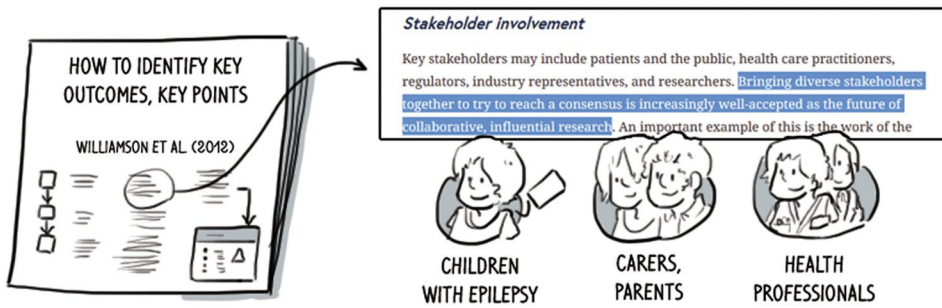
RESEARCHERS NOW INCREASINGLY BELIEVE IN THE IMPORTANCE OF IDENTIFYING A CORE SET OF OUTCOMES TO BE EVALUATED AND REPORTED IN ALL STUDIES ASSESSING INTERVENTIONS FOR SPECIFIC CONDITIONS.



INDEED, IT IS THOUGHT THIS COULD IMPROVE THE USEFULNESS OF RESEARCH, BY IDENTIFYING OUTCOMES MORE IMPORTANT TO PATIENTS AND CARERS.



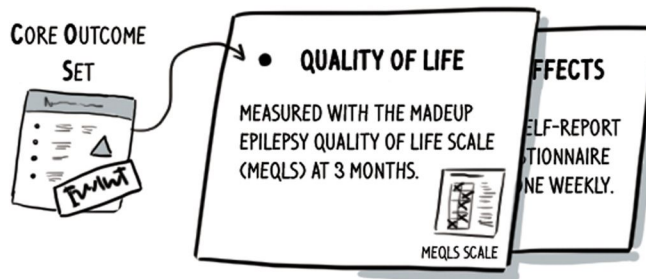
... AND AVOID WASTE BY MAKING RESULTS COMPARABLE BETWEEN STUDIES.



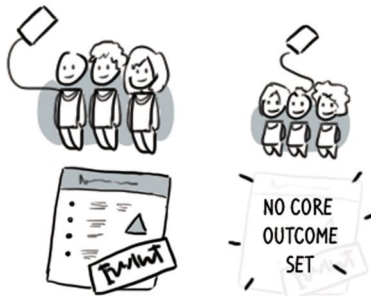
BEST PRACTICE GUIDES RECOMMEND THE DEVELOPMENT OF A CORE OUTCOME SET (COS) SHOULD, AT THE LEAST, INCLUDE THE VIEWS OF PATIENTS, CARERS AND HEALTH PROFESSIONALS.



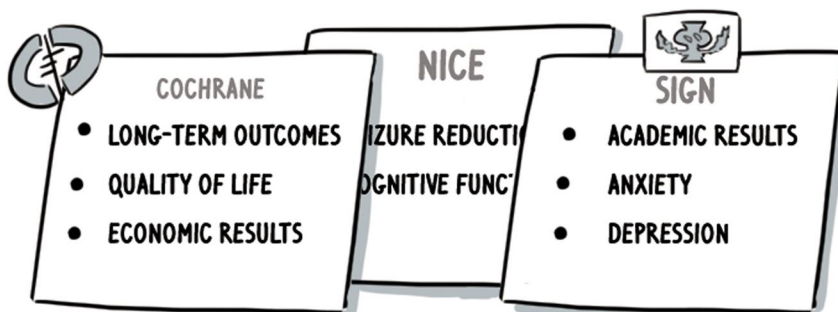
INVOLVEMENT OF CHILDREN AND PARENTS IS CRUCIAL TO ENSURE THE OUTCOMES MEASURED ARE MEANINGFUL AND THAT ASSESSMENT TOOLS ARE APPROPRIATE AND ACCEPTABLE.



A COS SPECIFIES BOTH WHAT ASPECTS OF HEALTH SHOULD BE ASSESSED AND HOW THOSE WILL BE MEASURED.



CURRENTLY THERE IS NO ESTABLISHED CORE OUTCOME SET FOR CHILDREN AND YOUNG PEOPLE WITH EPILEPSY, ALTHOUGH THERE IS SOME GUIDANCE FOR ADULTS.



AS AN EXAMPLE, ORGANIZATIONS SUCH AS COCHRANE, NICE AND SIGN* RECOMMEND INCLUDING THE FOLLOWING KEY OUTCOMES:

*COCHRANE, NICE AND SIGN ARE PRODUCERS OF RESEARCH STUDIES AND HEALTH GUIDELINES



THE AIM OF THIS WORK IS THEREFORE TO IDENTIFY A CORE SET OF OUTCOME MEASURES FOR ROLANDIC EPILEPSY.

METHODS



THE STUDY WILL FOLLOW THE PROCEDURES SET BY THE CORE OUTCOME MEASURES IN EFFECTIVENESS TRIALS (COMET) INITIATIVE AND DESCRIBED BELOW.



THE RESEARCHERS WILL SEEK ETHICAL APPROVAL THROUGH THE NATIONAL HEALTH SERVICE (NHS) HEALTH RESEARCH AUTHORITY.

SCOPE

POPULATION



THE STUDY WILL FOCUS ON ALL INTERVENTIONS FOR CHILDREN OF SCHOOL AGE (5–16 YEARS OLD) WITH ROLANDIC EPILEPSY.

PUBLIC INVOLVEMENT IN THIS RESEARCH

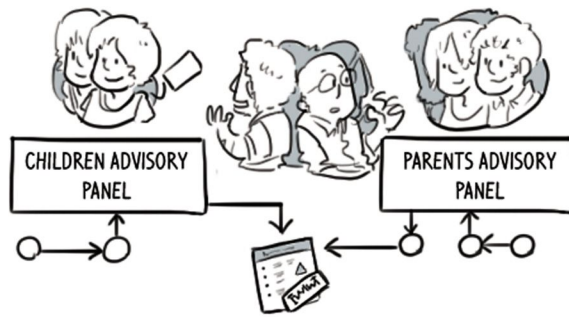


CHILDREN ADVISORY
PANEL



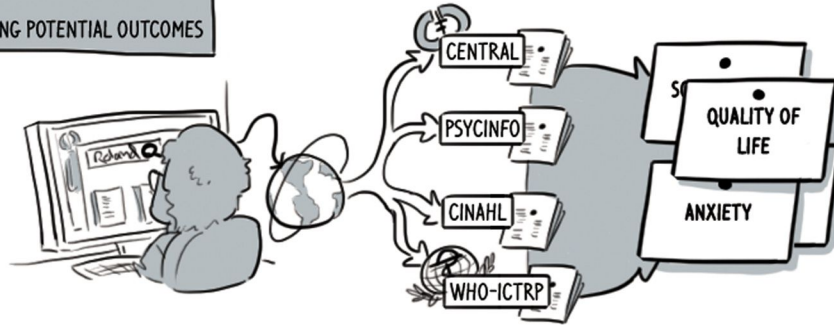
PARENTS ADVISORY
PANEL

TWO ADVISORY PANELS WILL BE CREATED, ONE WITH CHILDREN AND YOUNG PEOPLE WITH EPILEPSY AND ONE WITH PARENTS OF CHILDREN WITH EPILEPSY.



THE ADVISORY PANELS WILL BE CONSULTED AT ALL STAGES OF THE RESEARCH WHERE KEY INFLUENTIAL DECISIONS ARE REQUIRED.

1 STEP 1:
IDENTIFYING POTENTIAL OUTCOMES



POTENTIAL OUTCOME DOMAINS (E.G. QUALITY OF LIFE) WILL BE IDENTIFIED FROM RESEARCH STUDIES FOUND THROUGH SEARCHES RUN IN VARIOUS HEALTH DATABASES.

SEARCH STRATEGY:

CINAHL (5 JANUARY 2018) - 50 HITS

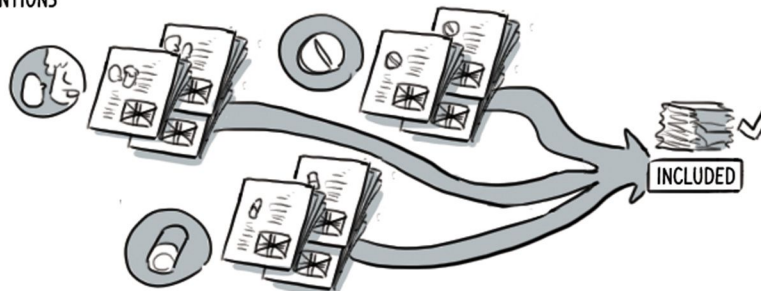
"ROLANDIC EPILEPSY" AND INTERVENTION* AND "KEYWORD2" AND "KEYWORD3", ETC.



THE SEARCH STRATEGY, KEYWORDS USED AND DATES OF SEARCHES WILL BE RECORDED AND REPORTED.

ONLY STUDIES WRITTEN IN ENGLISH WILL BE INCLUDED.

INTERVENTIONS

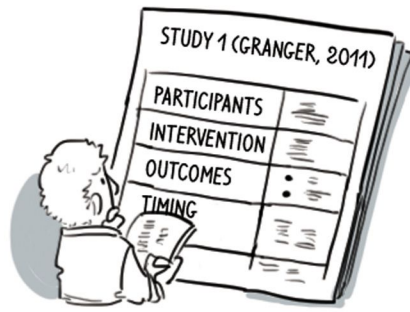


AND THE AUTHORS WILL INCLUDE STUDIES ON ALL TYPES OF INTERVENTIONS THAT AIM TO IMPROVE THE HEALTH OF CHILDREN WITH ROLANDIC EPILEPSY.

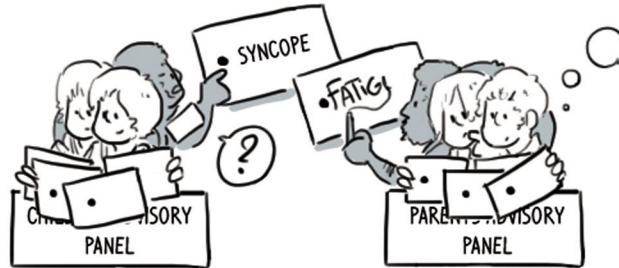


A SINGLE RESEARCHER* WILL THEN DECIDE IF STUDIES SHOULD BE INCLUDED AND RECORD DETAILS RELEVANT TO THE STUDY AIM.

*WITH HELP FROM OTHER MEMBERS OF THE RESEARCH TEAM IF THERE ARE DOUBTS



A SECOND RESEARCHER WILL THEN CHECK THAT RECORDED DETAILS ARE ACCURATE.



THE ADVISORY PANELS WILL THEN REVIEW THE LIST OF POTENTIAL OUTCOMES AND MAY ADD POTENTIAL NEW OUTCOMES OR CHANGE WORDING TO MAKE THEM MORE ACCESSIBLE.

2 STEP 2:
RATING THE IMPORTANCE OF OUTCOMES



THE RESEARCHERS WILL CONTACT FAMILIES, CHARITIES AND HEALTH PROFESSIONAL SOCIETIES IN THE UK TO ADVERTISE THE OPPORTUNITY TO PARTICIPATE IN AN ONLINE "DELPHI" SURVEY.



ALL POTENTIAL PARTICIPANTS WILL BE INVITED TO PARTICIPATE THROUGH AN ONLINE SYSTEM OR BY CONTACTING THE STUDY AUTHORS.



THE CHILDREN WILL ALSO BE OFFERED THE OPTION TO ANSWER INDEPENDENTLY FROM THEIR PARENTS.



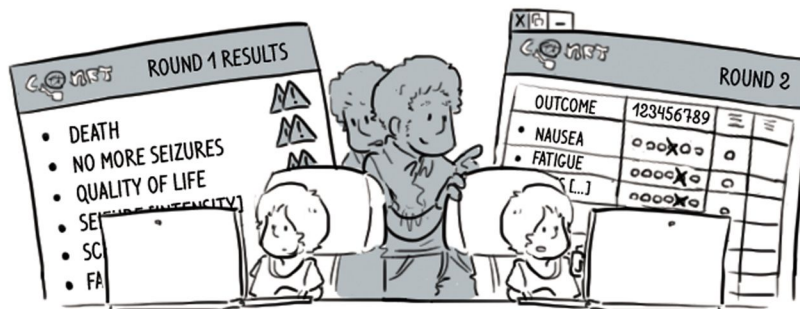
THE AUTHORS WANT TO INCLUDE FROM 20 TO 100 PARTICIPANTS AS THERE ARE NO DEFINITE RECOMMENDATIONS FOR THE NUMBER OF PARTICIPANTS TO INCLUDE IN SUCH SURVEYS.



FIRST, PARTICIPANTS WILL BE ASKED TO RATE THE LIST OF OUTCOMES IDENTIFIED IN STEP 1 USING A 9 POINT SCALE.

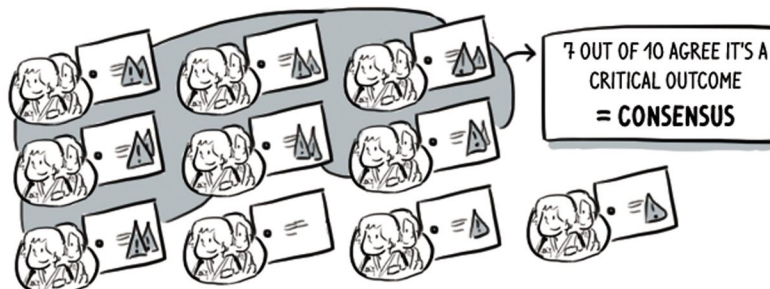
	CRITICAL			I'M NOT SURE	FEEDBACK
	7	8	9		
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THEY WILL ALSO HAVE THE OPTION TO EXPLAIN THEIR RESPONSES, RAISE ISSUES, SUGGEST A NEW OUTCOME DOMAIN OR RESPOND "NOT SURE".



IN THE NEXT 2-3* SURVEY ROUNDS PARTICIPANTS WILL SEE THEIR OWN AND OTHER PARTICIPANTS RESPONSES AND WILL BE ASKED TO RATE THE IMPORTANCE OF EACH OUTCOME AGAIN.

*PARTICIPANTS WILL DECIDE IF THERE WILL BE 2 OR 3 SURVEY ROUNDS



IF AT LEAST 70% PARTICIPANTS OF A STAKEHOLDER GROUP (FAMILIES OR PROFESSIONALS) AGREE ON THE IMPORTANCE OF AN OUTCOME THE AUTHORS WILL CONSIDER THIS A CONSENSUS.



FINALLY, A FACE TO FACE MEETING WITH 20 PARTICIPANTS WILL BE CONDUCTED TO RATIFY CONSENSUS ON KEY OUTCOME DOMAINS AND DEBATE INCLUDING ANY OUTCOME WHERE THERE IS DISAGREEMENT.

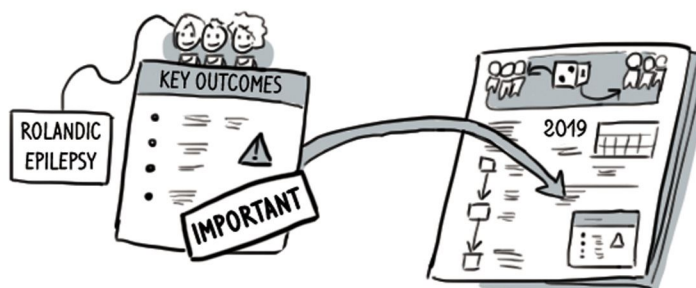
(NOT DESCRIBED HERE FOR BREVITY)

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STEP 3:
HOW TO MEASURE THE KEY OUTCOME DOMAINS



WHEN THE STUDY IS COMPLETED, THE AUTHORS WILL PRODUCE A PLAIN LANGUAGE SUMMARY, AN EASY-TO-READ VERSION FOR CHILDREN AND SHARE THEIR RESULTS ON SOCIAL MEDIA.



THE FINDINGS OF THIS STUDY WILL ALSO INFORM DECISIONS ABOUT OUTCOMES TO BE MEASURED IN A RANDOMIZED TRIAL WHICH WILL BEGIN RECRUITING IN 2019.

STUDY STATUS ON APRIL 10, 2018

THE STUDY IS ONGOING.

DECLARATIONS OF INTERESTS

THE AUTHORS DECLARE THAT THEY HAVE NO COMPETING INTERESTS.

STUDY FUNDING

THIS STUDY IS PART OF CHANGING AGENDAS ON SLEEP, TREATMENT AND LEARNING IN CHILDHOOD EPILEPSY (CASTLE), WHICH IS FUNDED BY THE NATIONAL INSTITUTE FOR HEALTH RESEARCH (NIHR) PROGRAMME GRANTS FOR APPLIED RESEARCH RP-PG-0615-20007. THE VIEWS AND OPINIONS EXPRESSED IN THIS PAPER ARE THOSE OF THE AUTHORS AND NOT NECESSARILY THOSE OF THE NHS, THE NIHR, OR THE DEPARTMENT OF HEALTH. TWO PARENTS OF CHILDREN WITH EPILEPSY WHO ALSO HAVE EXPERIENCE OF EPILEPSY THEMSELVES CO-AUTHORED THIS STUDY PROTOCOL, HELPED SECURE FUNDING AND ARE MEMBERS OF THE RESEARCH TEAM.

ACKNOWLEDGMENTS

SPECIAL THANKS TO CHRISTOPHER MORRIS FOR HIS WILLINGNESS TO COMMENT AND REVIEW THE WRITTEN AND ILLUSTRATED DRAFTS OF THIS ILLUSTRATION.

NOTES

SOME DETAILS IN THIS ILLUSTRATION MAY DIFFER FROM THE PUBLISHED CHOICE STUDY PROTOCOL (E.G. 2-3 SURVEY ROUNDS INSTEAD OF 3). THOSE CHANGES WERE POINTED OUT BY CHRISTOPHER MORRIS WHEN REVIEWING MY DRAFT.



FREE ACCESS TO THE STUDY VIA GOOGLE:
"ROLANDIC EPILEPSY MORRIS 10.1186"



MORRIS, C., DUNKLEY, C., GIBBON, F. M., CURRIER, J., ROBERTS, D., ROGERS, M., ... PAL, D. K. (2017). CORE HEALTH OUTCOMES IN CHILDHOOD EPILEPSY (CHOICE): PROTOCOL FOR THE SELECTION OF A CORE OUTCOME SET. TRIALS, 18(1). [HTTPS://DOI.ORG/10.1186/S13063-017-2323-7](https://doi.org/10.1186/s13063-017-2323-7)