Article title: The Burden of Caring for Individuals with Tuberous Sclerosis Complex (TSC) Who Experience Epileptic Seizures: A Descriptive UK Survey

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Conflicts of interest: All authors met the ICMJE authorship criteria and had full access to relevant data. Neither honoraria nor payments were made for authorship. Sally Bowditch, Edward Dziadulewicz and Kishan Vyas are employees of Jazz Pharmaceuticals, Inc. Sally Bowditch and Edward Dziadulewicz hold stock/stock options in Jazz Pharmaceuticals, Inc. Hanna Skrobanski, Lena Hubig and Siu Hing Lo are employees of Acaster Lloyd Consulting Ltd which received payment by GW Pharmaceuticals, now a part of Jazz Pharmaceuticals, Inc., in the conduct of this study. Louise Fish was an employee of Tuberous Sclerosis Association (TSA) when the study was conducted and Pooja Takhar is an employee of TSA; TSA has received sponsorship for events, an unrestricted educational grant, and consulting fees from GW Pharmaceuticals, now a part of Jazz Pharmaceuticals, Inc.

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Participant information and consent

TITLE:	Tuberous Sclerosis Complex (TSC): Caregiver Burden Survey
PROTOCOL NO.:	ALC1123
	IRB Protocol #20211736
SPONSOR:	GW Pharmaceuticals
INVESTIGATOR:	Siu Hing Lo, PhD, MA, MSc
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STUDY-RELATED PHONE NUMBER(S):	+ 44 (0)20 3978 1687

We are recruiting caregivers of people with Tuberous Sclerosis Complex (TSC) to take part in a research study. The study involves completing an online survey which should take approximately 20 to 30 minutes. We would like to learn about how you and your family are impacted by caring for a person with TSC.

A donation of £20 will be made to the Tuberous Sclerosis Association (TSA), as a token of appreciation for your time. Please read this information carefully before you decide whether or not you want to take part.

You will not be paid for being in this study.

Requirements for participation

Participants must be a main, unpaid caregiver of someone with TSC. All participants must also be aged 18 and over and live with the person with TSC they care for.

Participation is voluntary. It is possible that you may find some of the questions sensitive or upsetting. You do not have to answer any questions you find uncomfortable and are free to stop completing the survey at any time. As some questions can be personal, you will also have the option of selecting 'prefer not to answer' for some questions.

If you have any questions, concerns or complaints about the study, or if you feel you were

harmed by the research, please contact us using the email or phone number provided below.

How your data will be used

Your data will be used to help us understand the impact that looking after someone with TSC has on caregivers and wider family members. Once the survey is completed, your anonymous data will be combined with data from other caregivers and analysed by members of the research team. No identifying personal information will be recorded. In other words, we will not collect any data that would identify you as an individual, such as your name, date of birth, address or contact details.

Please note that because we cannot identify your data, we would not be able to remove any responses you have provided at a later stage if you wished us to do so.

The aggregate study results will be used to help healthcare decision-makers (such as NICE in the UK) understand the impact of TSC on people's lives. We anticipate that the combined study results will be presented at academic conferences and published in peer-reviewed medical journals. We also plan to share the aggregate results with patient organizations supporting the TSC community (e.g., TSA).

Confidentiality and data privacy

All research will be conducted in accordance with the EU General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018, and therefore, all information will be treated confidentially and only used for the research purposes stated above. All data will be held on secure servers of Acaster Lloyd Consulting Ltd within the EU or UK for a period of five years. The data you provide will not be connected to any of your personal identifying information by any members of the research team analysing and reporting the results. The study report and any publications or presentations about the study will only present aggregate study results and not contain any participant identifying information.

Adverse event reporting

It is a legal requirement that the sponsoring pharmaceutical company collects and keeps records of any Adverse Events, Product Complaints or unintended beneficial effects that people may have when using its medicines. We are therefore required to pass on details of an Adverse Event or Product Complaint to the sponsoring pharmaceutical company for any of its medicines mentioned during the study.

If you make any reference, in the survey, to an Adverse Event, Product Complaints or unintended beneficial effects regarding one of the commissioning pharmaceutical company's

medicines, we will forward this information to the Drug Safety team of the sponsoring company.

Researcher Contact Details

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This research is being overseen by WCG IRB. An IRB is a group of people who perform independent review of research studies. You may talk to them at 855-818-2289 or researchquestions@wcgirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

Participant Informed Consent

Please read the following about your rights as a research participant. Once you have read the text, please tick the box to confirm that you understand and agree with each statement.

☐ I have received information about the study and had sufficient time to read through it.

☐ I voluntarily give my consent to the study. I know I can stop completing the survey at any time.

☐ I agree to the recording of the data I provide in the survey and understand that the researchers will not be able to remove data once the survey is completed because no personal identifiable information will be recorded.

☐ I agree that my anonymous data can be passed on to members of the research team to be used for data processing and scientific analysis.

☐ I give my consent to share the aggregate study results with healthcare decision-

makers and patient organizations while adhering to data protection legislation such as the EU General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.

- ☐ I give my consent to the scientific publication of the aggregate study results while adhering to data protection legislation such as the EU General Data Protection Regulation (GDPR) and the UK Data Protection Act 2018.

Are you happy to take part in this study?

- ☐ I wish to take part in this study
- ☐ I DO NOT wish to take part in this study

If you wish, you can print or save a copy of this consent text to keep for your records.