

**Methodological review to identify analysis methods for assessing
interrupted time series data: Protocol**

Protocol version: 1

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Version history

Amendment No.	Protocol version No.	Description of changes	Date of protocol
	Version 1	New document	

Background

Robust analysis methods are needed for experimental designs to demonstrate causality between an intervention and an outcome. For interrupted time series (ITS) studies there are several methodology challenges in ITS studies that need to be considered:

Autocorrelation – observations collected closely together are correlated with each. It is important to take into account autocorrelation as it can cause results to either be underestimated or overestimated.

Nonstationary (secular trend) – this is where the outcome is either increasing or decreasing over time irrespective of the intervention.

Seasonality or cyclical effects– occurs when the outcome data over time follows a pattern.

Moving-average process – this is where the current observations are a linear combination of past observations.

The aim of this study is to conduct a systematic review across all disciplines to identify all possible analysis methods of ITS data. To describe each method and provide possible strengths and weaknesses of each method found.

Search strategy

An electronic search will be undertaken to identify ITS methods in MEDLINE, Web of science, EconLit, EconPapers and PsycINFO. The search strategy will mainly consist of text words and phrases using truncation symbols and adjacency operators. A detailed search strategy for each database is documented in Appendix 1.1. For MEDLINE and PsycINFO deduplication will be performed in Ovid, and for Web of science, health categories will be removed as these studies should be picked up in MEDLINE. Of the abstracts found, 10% (from each database) will be double assessed for inclusion and any disagreements will be resolved.

Each searched database will be done intern: MEDLINE, Web of science, EconLit, EconPapers and PsycINFO. They will be searched in intervals of 25% and after each interval full text papers of the potentially identified abstracts and titles will be assessed for inclusion. This will enable to identify any potential new ITS methods and therefore if these methods

appear in later abstracts or titles there will be no need to include these studies to full text. If at any stage it is unclear if an analysis method is eligible, the final decision will be made once all the databases and full texts have been screened. Of the full text articles 10% (from each database) will be double assessed for inclusion and any disagreements will be resolved.

Inclusion and exclusion criteria

An ITS analysis method will be eligible for inclusion if:

- there is a defined time point of when the intervention occurred, and the analysis method looks to see whether this intervention at that time point had an effect on the outcome.
- the data had at least two data points before the intervention and one after.

There will be no restriction on the type of outcome, subject, publication type and language, or intervention. Meta-analysis, randomised trials, and studies with a separate control group will be excluded.

A screening form (Appendix 1.2) will be used to identify studies that will be included in the review.

Data extraction strategy

Of the identified methods relevant details will be recorded on a data extraction form (Appendix 1.3). Description of the analysis method, any assumptions made, outcome type, and whether the paper was the original methods paper will be extracted. As well as strengths and limitations of the methods. Either 10% of the full text papers will be assessed or if there are a limited number found then all will be double assessed.

Appendix 1.1: Search strategy

MEDLINE (In-Process & Other Non-Indexed Citations and Ovid MEDLINE® 1946 to Present) and PsycINFO

1. interrupted time series.tw,kw.
2. (segmented adj3 regression\$.tw,kw.
3. arima.tw,kw.
4. autoregressive integrated moving average.tw,kw.
5. intervention analysis.tw,kw.
6. intervention time series.tw,kw.
7. time series regression\$.tw,kw.
8. or/1-7
9. meta analys\$.ti.
10. randomi\$ control\$ trial\$.ti.
11. 8 not (9 or 10)
12. limit 11 to yr="2005-2018"
13. remove duplicates from 12
14. 11
15. limit 14 to yr="1860 - 2004"
16. remove duplicates from 15
17. 13 or 16

Web of Science (Science Citation Index Expanded)

#12	<p>#10 NOT (#8 OR #9)</p> <p>Refined by: [excluding]: WEB OF SCIENCE CATEGORIES: (PERIPHERAL VASCULAR DISEASE OR PUBLIC ENVIRONMENTAL OCCUPATIONAL HEALTH OR MEDICINE GENERAL INTERNAL OR GASTROENTEROLOGY HEPATOLOGY OR HEALTH CARE SCIENCES SERVICES OR PSYCHOLOGY OR CARDIAC CARDIOVASCULAR SYSTEMS OR ANESTHESIOLOGY OR NURSING OR INFECTIOUS DISEASES OR OBSTETRICS GYNECOLOGY OR PHYSIOLOGY OR UROLOGY NEPHROLOGY OR TROPICAL MEDICINE OR ONCOLOGY OR PHARMACOLOGY PHARMACY OR MEDICAL INFORMATICS OR HEALTH POLICY SERVICES OR RESPIRATORY SYSTEM OR EMERGENCY MEDICINE OR MEDICINE RESEARCH EXPERIMENTAL OR SURGERY OR OPHTHALMOLOGY OR PSYCHIATRY OR ORTHOPEDICS OR NUTRITION DIETETICS OR CLINICAL NEUROLOGY OR CRITICAL CARE MEDICINE OR SOCIAL SCIENCES MATHEMATICAL METHODS OR NEUROSCIENCES OR REHABILITATION OR RADIOLOGY NUCLEAR MEDICINE MEDICAL IMAGING OR GERIATRICS GERONTOLOGY OR SUBSTANCE ABUSE OR ENDOCRINOLOGY METABOLISM)</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#11	<p>#10 NOT (#8 OR #9)</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#10	<p>#7 OR #6 OR #5 OR #4 OR #3 OR #2 OR #1</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#9	<p>Ti=randomi* control* trials*</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#8	<p>Ti="meta analys**"</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#7	<p>Ts="time series regression"</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#6	<p>Ts="intervention time series"</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#5	<p>Ts="intervention analysis"</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#4	<p>Ts = "autoregressive integrated moving average"</p> <p><i>DocType=All document types; Language=All languages;</i></p>
#3	<p>Ts=arima</p> <p><i>DocType=All document types; Language=All languages;</i></p>

#2	Ts=(segmented NEAR regression) <i>DocType=All document types; Language=All languages;</i>
#1	Ts=interrupted time series <i>DocType=All document types; Language=All languages;</i>

EconLit and Econ papers (Working papers only)

"interrupted time series" OR "segmented regression" OR arima OR "autoregressive integrated moving average" OR "time series regression" OR "intervention time series"

Appendix 1.2: Abstract and Title Screening Form

1. Is the study a meta-analysis or a randomised control trial?
- Yes —————→ Exclude
- No
- ↓
2. Is the analysis method for interrupted time series data with a clear intervention time point and a minimum of two data points before and one after the intervention?
- Yes
- No —————→ Exclude
- Unsure
- ↓
- a. Does it compare different statistical methods?
- Yes
 - No
- ↓
3. Is there a separate control group?
- Yes —————→ Exclude
- No
- Unsure
- ↓
4. Is the analysis a new method?
- Yes
- No —————→ Exclude
- Unsure
- ↓
5. Is the study to be included to full text?
- Yes
- No

Appendix 1.3: Data Extraction Form

Study ID (<i>surname of first author and year first full report of study was published</i>)

Eligibility – review inclusion criteria	
Is the analysis method for interrupted time series data with a minimum of two data points before and one after the intervention?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the analysis a new method?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Does the study have a separate control/comparison group?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Is the analysis a new method?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Decision	<input type="checkbox"/> Include <input type="checkbox"/> Exclude
Does it compare different interrupted time series statistical methods?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Characteristics	
Description of method	
Assumptions of the analysis	
Outcome type	<input type="checkbox"/> Continuous <input type="checkbox"/> Binary <input type="checkbox"/> Count <input type="checkbox"/> Other If other, please specify
Was it on individual subject data?	<input type="checkbox"/> Yes <input type="checkbox"/> No

Is this the original paper of the analysis method?	<input type="checkbox"/> Yes <input type="checkbox"/> No If no, please provide details/ reference to the analysis paper
Strengths of the method (indicate if this was specified by the author)	
Limitations of the method (indicate if this was specified by the author)	